



U.S. Department of Justice

Criminal Division

June 21, 2016

William H. Paine  
Jay Holtmeier  
Wilmer Cutler Pickering Hale and Dorr LLP  
60 State Street  
Boston, Massachusetts 02109

Re: BK Medical ApS

Dear Messrs. Paine and Holtmeier:

On the understandings specified below, the United States Department of Justice, Criminal Division, Fraud Section and United States Attorney's Office for the District of Massachusetts (collectively, the "Offices"), will not criminally prosecute BK Medical ApS ("BK Medical" or the "Company"), or any of its present or former parents or subsidiaries, for any crimes (except for criminal tax violations, as to which the Offices do not make any agreement) related to its knowing and willful falsification of the books, records, and accounts of its parent company Analogic Corporation, a U.S. issuer, under the Foreign Corrupt Practices Act ("FCPA"), Title 15, United States Code, Section 78m, and any of the conduct described in the Statement of Facts attached hereto as Attachment A. The Offices enter into this Non-Prosecution Agreement based on the individual facts and circumstances presented by this case and the Company. Among the factors considered in deciding what credit the Company should receive were the following:

- a) the Company, through its parent company Analogic Corporation ("Analogic"), voluntarily and timely disclosed to the Offices the conduct described in the Statement of Facts attached hereto as Attachment A, which were known to the Company at the time of the disclosure, and thus the Company received full credit for its voluntary disclosure;
- b) the Company did not receive full cooperation credit because, in the view of the Offices, the Company's cooperation subsequent to its self-disclosure did not include disclosure of all relevant facts that it learned during the course of its internal investigation; specifically, the Company did not disclose information that was known to the Company and Analogic about the identities of a number of the state-owned entity end-users of the Company's products, and about certain statements given by employees in the course of the internal investigation;
- c) except as provided in (b) above, by the conclusion of the investigation, the Company had provided to the Offices all relevant facts known to it, including information about individuals involved in the FCPA misconduct;
- d) the Company engaged in extensive remedial measures, including enhanced financial controls related to payments and invoicing, enhanced FCPA training, and a new

distributor due diligence program;

- e) accordingly, after considering (a) through (d) above, the Company received an aggregate discount of 30% off the bottom of the U.S. Sentencing Guidelines fine range;
- f) the Company has committed to continue to enhance its compliance program and internal controls, including ensuring that its compliance program satisfies the minimum elements set forth in Attachment B to this Agreement;
- g) based on the Company's remediation and the state of its compliance program, and that of its parent company Analogic, and the Company's agreement to report to the Offices as set forth in Attachment C to this Agreement, the Offices determined that an independent compliance monitor was unnecessary;
- h) the nature and seriousness of the offense, including that the Company engaged in an at least 10-year scheme to create fraudulent invoices to conceal approximately \$20 million in improper payments associated with the Company's distributors;
- i) the Company has no prior criminal history; and
- j) the Company has agreed to continue to cooperate with the Offices in any ongoing investigation of the conduct of the Company and its officers, directors, employees, agents, business partners, distributors, and consultants relating to violations of the FCPA, and to cooperate with foreign authorities that are prosecuting individuals involved in this matter.

The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as set forth in the Statement of Facts attached hereto as Attachment A and incorporated by reference into this Agreement, and that the facts described in Attachment A are true and accurate. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents or any other person authorized to speak for the Company make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the Statement of Facts attached hereto as Attachment A. The Company agrees that if it, its parent company, or any of its direct or indirect subsidiaries or affiliates issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult the Offices to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Offices and the Company; and (b) whether the Offices have any objection to the release.

The Company's obligations under this Agreement shall have a term of three years from the date on which the Agreement is executed (the "Term").

The Company shall cooperate fully with the Offices in any and all matters relating to the conduct described in this Agreement and Attachment A and other conduct related to corrupt payments, false books and records, failure to implement adequate internal accounting controls, and circumvention of internal controls under investigation by the Offices, subject to applicable law and regulations, until the later of the date upon which all investigations and prosecutions arising out of

such conduct are concluded, or the Term. At the request of the Offices, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies, as well as the Multilateral Development Banks ("MDBs"), in any investigation of the Company, its parent company or its affiliates, or any of its present or former officers, directors, employees, agents, and consultants, or any other party, in any and all matters relating to the conduct described in this Agreement and Attachment A and other conduct related to corrupt payments, false books and records, failure to implement adequate internal accounting controls, and circumvention of internal controls under investigation by the Office. The Company agrees that its cooperation shall include, but not be limited to, the following:

a. The Company shall truthfully disclose all factual information not protected by a valid claim of attorney-client privilege or work product doctrine with respect to its activities, those of its parent company and affiliates, and those of its present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the Company has any knowledge or about which the Offices may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Offices, upon request, any document, record or other tangible evidence about which the Offices may inquire of the Company.

b. Upon request of the Offices, the Company shall designate knowledgeable employees, agents or attorneys to provide to the Offices the information and materials described above on behalf of the Company. It is further understood that the Company must at all times provide complete, truthful, and accurate information.

c. The Company shall use its best efforts to make available for interviews or testimony, as requested by the Offices, present or former officers, directors, employees, agents and consultants of the Company. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with domestic or foreign law enforcement and regulatory authorities. Cooperation shall include identification of witnesses who, to the knowledge of the Company, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records or other tangible evidence provided to the Offices pursuant to this Agreement, the Company consents to any and all disclosures, subject to applicable law and regulations, to other governmental authorities, including United States authorities and those of a foreign government, as well as MDBs, of such materials as the Offices, in their sole discretion, shall deem appropriate.

In addition, during the Term of the Agreement, should the Company learn of credible evidence or allegations of possible corrupt payments, the Company shall promptly report such evidence or allegations to the Offices. No later than thirty (30) days after the expiration of the Term of this Agreement, the Company, by the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, will certify to the Department that the Company has met its disclosure obligations pursuant to this Agreement. Such certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001.

The Company represents that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the Foreign Corrupt

Practices Act and other applicable anti-corruption laws throughout its operations, including those of its affiliates, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities include interacting with foreign officials or other activities carrying a high risk of corruption, including, but not limited to, the minimum elements set forth in Attachment B, which is incorporated by reference into this Agreement. In addition, the Company agrees that it will report to the Offices annually during the Term of the Agreement regarding remediation and implementation of the compliance measures described in Attachment B. These reports will be prepared in accordance with Attachment C.

The Company agrees to pay a monetary penalty in the amount of \$3,402,000 to the United States Treasury within ten (10) business days from the execution of the Agreement. This monetary penalty is in excess of the \$7,672,651 disgorgement of profits by the Company in connection with its resolution with the Securities and Exchange Commission in a related matter. The Company acknowledges that no tax deduction may be sought in connection with the payment of any part of this \$3,402,000 penalty.

The Offices agree, except as provided herein, that they will not bring any criminal or civil case against the Company or any of its present or former parents, or subsidiaries, relating to any of the conduct described in the Statement of Facts, attached hereto as Attachment A. The Offices, however, may use any information related to the conduct described in the attached Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code. This Agreement does not provide any protection against prosecution for any future conduct by the Company. In addition, this Agreement does not provide any protection against prosecution of any present or former officer, director, employee, shareholder, agent, consultant, contractor, or subcontractor of the Company for any violations committed by them.

If, during the Term of this Agreement, the Company (a) commits any felony under U.S. federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading information; (c) fails to cooperate as set forth in this Agreement; (d) fails to implement a compliance program as set forth in this Agreement and Attachment C; (e) commits any acts that, had they occurred within the jurisdictional reach of the Foreign Corrupt Practices Act, would be a violation of the Foreign Corrupt Practices Act; or (f) otherwise fails specifically to perform or to fulfill completely each of the Company's obligations under the Agreement, regardless of whether the Offices become aware of such a breach after the Term of the Agreement is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the Offices have knowledge, including, but not limited to, the conduct described in the attached Statement of Facts, which may be pursued by the Offices in the U.S. District Court for the District of Massachusetts or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company shall be in the Offices' sole discretion. Any such prosecution may be premised on information provided by the Company. Any such prosecution relating to the conduct described in the attached Statement of Facts or relating to conduct known to the Offices prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled

for the term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of U.S. federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Office is made aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

In the event the Offices determine that the Company has breached this Agreement, the Offices agree to provide the Company with written notice of such breach prior to instituting any prosecution resulting from such breach. Within thirty (30) days of receipt of such notice, the Company shall have the opportunity to respond to the Offices in writing to explain the nature and circumstances of such breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Offices shall consider in determining whether to pursue prosecution of the Company.

In the event that the Offices determine that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Offices or to the Court, including the attached Statement of Facts, and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Offices against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Offices.

Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company agrees that in the event that, during the Term of the Agreement, it undertakes any change in corporate form, including if it sells, merges, or transfers a substantial portion of its business operations as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The Company shall obtain approval from the Offices at least thirty (30) days prior to undertaking any such sale, merger, transfer, or other change in corporate form, including dissolution, in order to give the Offices an opportunity to determine if such change in corporate form would impact the terms or obligations of the Agreement.

This Agreement is binding on the Company and the Offices but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the Offices will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

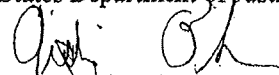
It is further understood that the Company and the Offices may disclose this Agreement to the public.

This Agreement sets forth all the terms of the agreement between the Company and the Offices. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Offices, the attorneys for the Company, and a duly authorized representative of the Company.

Sincerely,

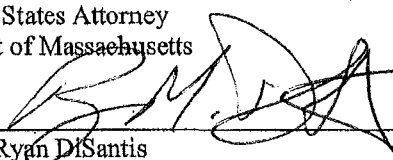
ANDREW WEISSMANN  
Chief, Fraud Section  
Criminal Division  
United States Department of Justice

Date: 6-21-16

BY:   
Aisling O'Shea  
Trial Attorney

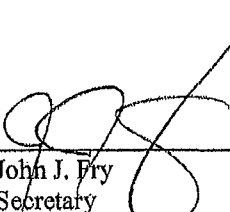
CARMEN M. ORTIZ  
United States Attorney  
District of Massachusetts

Date: 6-21-16

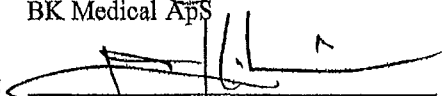
BY:   
Ryan DiSantis  
Assistant United States Attorney

AGREED AND CONSENTED  
TO:

Date: 6-21-16

BY:   
John J. Fry  
Secretary  
BK Medical ApS

Date: 6-21-16

BY:   
William H. Paine  
Jay Holtmeier  
Wilmer Cutler Pickering Hale and Dorr LLP  
Counsel to BK Medical ApS

## ATTACHMENT A

### **STATEMENT OF FACTS**

The following Statement of Facts is incorporated by reference as part of the non-prosecution agreement (the “Agreement”) between the United States Department of Justice, Criminal Division, Fraud Section and the United States Attorney’s Office for the District of Massachusetts and BK Medical ApS (“BK Medical”). BK Medical hereby agrees and stipulates that the following information is true and accurate. BK Medical admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below:

#### ***Analogic and BK Medical***

1. Analogic Corporation (“Analogic”) is a Massachusetts corporation headquartered in Peabody, Massachusetts. Analogic manufactures health care and security technology sold globally, including computed tomography, ultrasound, digital mammography, magnetic resonance imaging and aviation threat detection. Analogic’s common stock is registered with the Securities and Exchange Commission pursuant to Section 12(b) of the Securities Exchange Act of 1934 and is listed on the NASDAQ Global Select Market under the symbol ALOG. Therefore, Analogic is an “issuer” within the meaning of the Foreign Corrupt Practices Act, Title 15, United States Code, Sections 78dd-1(a) and 78m.

2. BK Medical ApS (“BK Medical”) is a wholly owned subsidiary of Analogic headquartered in Harlev, Denmark. BK Medical produces ultrasound equipment, which, depending on the geographic region, was either sold directly to clinical end-users or to third-party distributors, which in turn sold to clinical end-users. During the relevant period, in

Russia, BK Medical sold its products exclusively through distributors.

### ***BK Medical's Distributors and Customers***

3. During the relevant period, Distributor 1 was BK Medical's distributor in Russia. Distributor 1 would purchase ultrasound equipment from BK Medical and would in turn sell that equipment to clinical end-users in Russia.

4. BK Medical's employees were aware that ultimate sales by its distributor in Russia were to hospitals or other medical facilities that were controlled by the government of Russia and performed functions that the Russian government treated as its own, and thus were instrumentalities of the Russian government as that term is used in the Foreign Corrupt Practices Act ("FCPA"), Title 15, United States Code, Section 78dd-3(f)(2). Employees of these customers were therefore "foreign officials" as that term is used in the FCPA, Title 15, United States Code, Section 78dd-3(f)(2). BK Medical employees were aware that many of its end-users were Russian state-owned entities whose employees were Russian government officials.

### ***The Improper Payments***

5. From at least 2001 through early 2011, BK Medical engaged in a scheme to channel approximately \$20 million in improper payments to various third parties and to conceal those payments by creating fictitious invoices and causing its parent corporation, Analogic, to falsify its books and records.

6. For example, BK Medical engaged in hundreds of transactions with Distributor 1 wherein after the actual terms of a purchase of equipment had been agreed upon, and after BK Medical had invoiced Distributor 1 for the equipment, Distributor 1 would request that BK



Medical provide Distributor 1 with a second invoice reflecting an inflated sales price.

7. Following these requests from Distributor 1, BK Medical employees would create a fictitious invoice (commonly referred to at BK Medical as a “special” invoice) outside the normal invoice-generation and accounting system that reflected an inflated amount of payment due to BK Medical, as requested by Distributor 1. At the time these invoices were prepared, BK Medical employees were aware that they did not reflect the true purchase price for the equipment, and instead reflected an inflated sales price that had been requested by Distributor 1. Thus, BK Medical would keep two invoices in its books and records – a correct invoice created pursuant to the Company’s accounting procedures, and a fictitious invoice created outside these procedures.

8. BK Medical would then provide the fictitious invoice to Distributor 1, which would subsequently make payment against the inflated invoice, resulting in an overpayment to BK Medical. BK Medical would hold the excess funds in accounts receivable.

9. At some point after the excess payment was made, Distributor 1 would direct BK Medical to wire a payment to a third-party recipient from the excess funds in BK Medical’s custody resulting from the overpayment. None of these third-party recipients had a business connection to BK Medical of which BK Medical was aware, and BK Medical did not conduct any due diligence on these recipients, but merely sent them money at Distributor 1’s direction. Some of these third-party recipients were named individuals, while others were shell companies.

10. On certain occasions, Distributor 1 would send BK Medical an invoice that purported to be from the third-party entity that was to receive a payment from BK Medical.

These invoices referred to services being rendered to BK Medical as, among other things, “marketing,” “logistic service,” and “commission.” BK Medical employees have confirmed that none of these entities actually rendered any services to BK Medical and that they understood this fact at the time these invoices were received by BK Medical. Payments to the third parties, including the third-party entities that submitted invoices to BK Medical, were made from the accounts receivable system. As a consequence, the third-party entities were not subject to Analogic’s required vendor approval process for payments made from the accounts payable system.

11. On at least two occasions, BK Medical made payments to third parties at the direction of Distributor 1 using its own funds prior to being reimbursed by Distributor 1 because, at the time the payments were requested by Distributor 1, BK Medical was not holding any excess funds from Distributor 1 on its books.

12. There is evidence that at least some of these payments to third parties were ultimately to doctors employed by Russian state-owned entities.

13. For example, on or about May 5, 2004, a BK Medical employee wrote an e-mail to an employee of Distributor 1, providing a draft explanation of the overpayments, which the Distributor 1 employee could then send back to BK Medical. The e-mail stated: “Please note that this is simply a part of the Russian market conditions and it is a result of our process going from the former Soviet planning economy to the more western and democratic market economy. It will take many years before we will reach a real market economy and the level of official salaries in many sectors are extremely low which makes it impossible to maintain a reasonable standard of living. The money we request you to transfer are not in anyway money for

[Distributor 1], you already know about this, but is is [sic] for various obligations that is not in our control. We know that sometimes that money goes back into the regions for education and training, which under normal conditions would not be possible, but also for general improvement of the living standard among a lot of different persons, not only persons on high levels...If you cannot continue to help us with the money transfers, we will risk up to 90% of our B-K business...Please understand that your Western word 'bribe' is not used in our Russian market...

14. While the scheme with Distributor 1 was the most extensive, totaling approximately \$16 million in improper payments and false accounting, BK Medical also received overpayments, issued fictitious invoices, and made payments to unknown third-party recipients in agreement with its distributors in five other countries.

***Causing Analogic to Falsify Its Books, Records, and Accounts***

15. During the relevant time period, BK Medical caused Analogic to falsify its books, records, and accounts in connection with the improper payment scheme. As a wholly owned subsidiary of Analogic that was responsible for Analogic's ultrasound division and whose financials were consolidated into Analogic's books, records, and accounts, BK Medical was required to provide representations and certifications to Analogic about BK Medical's financials and financial controls.

16. For example, BK Medical was required to complete division quarterly review checklists (the "checklists") and submit them to Analogic's controller. Among other things, these checklists required BK Medical to report on any side letters that modified existing contract terms, confirm whether there were any internal controls issues to report, confirm compliance with all Analogic corporate accounting policies, and certify that BK Medical's financial records

were in accordance with U.S. GAAP. In each quarter that Analogic required the checklists, certain BK Medical executives provided the required confirmations and certifications, but never reported the overpayments or third-party payments even though those executives knew about the improper payments.

17. BK Medical was also required to provide certifications of BK Medical's financial statements for Sarbanes-Oxley consolidation purposes (the "subcertifications") prior to the issuance of Analogic's quarterly reports. In relevant part, the subcertifications required a BK Medical executive to certify that "all material financial transactions of the subsidiaries for which I am responsible have been properly recorded on the books of the subsidiaries, and there have been no intentionally false or misleading statements, entries, or omissions made in connection with my activities or the activities of my subsidiaries." In each quarter that Analogic required the subcertifications, the BK Medical executive certified "true without exception," and again failed to report the overpayments or third-party payments in spite of this executive's knowledge of the payments.

18. In addition, BK Medical maintained as part of its books, records, and accounts the fictitious invoices it issued to distributors, as well as the fictitious invoices it received from Distributor 1 purportedly from certain of the third-party entities receiving payment. These books, records, and accounts were consolidated into Analogic's books and records and reported by Analogic in its financial statements.

## ATTACHMENT B

### CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance codes, policies, and procedures regarding compliance with the Foreign Corrupt Practices Act (“FCPA”), 15 U.S.C. §§ 78dd-1, *et seq.*, and other applicable anti-corruption laws, BK Medical ApS (“BK Medical” or the “Company”) agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt new or to modify existing internal controls, compliance codes, policies, and procedures in order to ensure that it maintains: (a) a system of internal accounting controls designed to ensure that the Company makes and keeps fair and accurate books, records, and accounts; and (b) a rigorous anti-corruption compliance program that includes policies and procedures designed to detect and deter violations of the FCPA and other applicable anti-corruption laws. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company’s existing internal controls, compliance codes, policies, and procedures:

#### *High-Level Commitment*

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policies against violations of the anti-corruption laws and its compliance code.

## *Policies and Procedures*

2. The Company will develop and promulgate a clearly articulated and visible corporate policy against violations of the FCPA and other applicable foreign law counterparts (collectively, the “anti-corruption laws,”), which policy shall be memorialized in a written compliance code or codes.

3. The Company will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the anti-corruption laws and the Company’s compliance code, and the Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the anti-corruption laws by personnel at all levels of the Company. These anti-corruption policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company in a foreign jurisdiction, including but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners (collectively, “agents and business partners”). The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the Company. Such policies and procedures shall address:

- a. gifts;
- b. hospitality, entertainment, and expenses;
- c. customer travel;
- d. political contributions;

- e. charitable donations and sponsorships;
- f. facilitation payments; and
- g. solicitation and extortion.

4. The Company will ensure that it has a system of financial and accounting procedures, including a system of internal controls, reasonably designed to ensure the maintenance of fair and accurate books, records, and accounts. This system should be designed to provide reasonable assurances that:

a. transactions are executed in accordance with management's general or specific authorization;

b. transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and to maintain accountability for assets;

c. access to assets is permitted only in accordance with management's general or specific authorization; and

d. the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

*Periodic Risk-Based Review*

5. The Company will develop these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of the Company, in particular the foreign bribery risks facing the Company, including, but not limited to, its

geographical organization, interactions with various types and levels of government officials, industrial sectors of operation, involvement in joint venture arrangements, importance of licenses and permits in the Company's operations, degree of governmental oversight and inspection, and volume and importance of goods and personnel clearing through customs and immigration.

6. The Company shall review its anti-corruption compliance policies and procedures no less than annually and update them as appropriate to ensure its continued effectiveness, taking into account relevant developments in the field and evolving international and industry standards.

*Proper Oversight and Independence*

7. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's anti-corruption compliance codes, policies, and procedures. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, the Company's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of autonomy from management as well as sufficient resources and authority to maintain such autonomy.

*Training and Guidance*

8. The Company will implement mechanisms designed to ensure that its anti-corruption compliance code, policies, and procedures are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust, positions that require such training (e.g., internal



audit, sales, legal, compliance, finance), or positions that otherwise pose a corruption risk to the Company, and, where necessary and appropriate, agents and business partners; and (b) corresponding certifications by all such directors, officers, employees, agents, and business partners, certifying compliance with the training requirements.

9. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's anti-corruption compliance codes, policies, and procedures, including when they need advice on an urgent basis or in any foreign jurisdiction in which the Company operates.

#### *Internal Reporting and Investigation*

10. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the anti-corruption laws or the Company's anti-corruption compliance code, policies, and procedures.

11. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the anti-corruption laws or the Company's anti-corruption compliance code, policies, and procedures.

#### *Enforcement and Discipline*

12. The Company will implement mechanisms designed to effectively enforce its compliance codes, policies, and procedures, including appropriately incentivizing compliance

and disciplining violations.

13. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the anti-corruption laws and the Company's anti-corruption compliance codes, policies, and procedures by the Company's directors, officers, and employees. Such procedures should be applied consistently and fairly, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance codes, policies, and procedures and making modifications necessary to ensure the overall anti-corruption compliance program is effective.

*Third-Party Relationships*

14. The Company will institute appropriate risk-based due diligence and compliance requirements pertaining to the retention and oversight of all agents and business partners, including:

- a. properly documented due diligence pertaining to the hiring and appropriate and regular oversight of agents and business partners;
- b. informing agents, distributors, and business partners of the Company's commitment to abiding by anti-corruption laws, and of the Company's anti-corruption compliance code, policies, and procedures; and
- c. seeking a reciprocal commitment from agents and business partners.

15. Where necessary and appropriate, the Company will include standard provisions in agreements, contracts, and renewals thereof with all agents and business partners that are reasonably calculated to prevent violations of the anti-corruption laws, which may, depending upon the circumstances, include: (a) anti-corruption representations and undertakings relating to compliance with the anti-corruption laws; (b) rights to conduct audits of the books and records of the agent or business partner to ensure compliance with the foregoing; and (c) rights to terminate an agent or business partner as a result of any breach of the anti-corruption laws, the Company's compliance codes, policies, or procedures, or the representations and undertakings related to such matters.

#### *Mergers and Acquisitions*

16. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate FCPA and anti-corruption due diligence by legal, accounting, and compliance personnel.

17. The Company will ensure that the Company's compliance code, policies, and procedures regarding the anti-corruption laws apply as quickly as is practicable to newly acquired businesses or entities merged with the Company and will promptly:

- a. train the directors, officers, employees, agents, and business partners consistent with Paragraph 8 above on the anti-corruption laws and the Company's compliance code, policies, and procedures regarding anti-corruption laws; and
- b. where warranted, conduct an FCPA-specific audit of all newly acquired

or merged businesses as quickly as practicable.

*Monitoring and Testing*

18. The Company will conduct periodic reviews and testing of its anti-corruption compliance code, policies, and procedures designed to evaluate and improve their effectiveness in preventing and detecting violations of anti-corruption laws and the Company's anti-corruption code, policies, and procedures, taking into account relevant developments in the field and evolving international and industry standards.

ATTACHMENT C

**CORPORATE COMPLIANCE REPORTING**

BK Medical ApS (“BK Medical” or the “Company”) agrees that it will report to the Offices periodically, at no less than twelve-month intervals during a three-year Term, regarding remediation and implementation of the compliance program and internal controls, policies, and procedures described in Attachment B. Should the Company discover credible evidence, not already reported to the Offices, that questionable or corrupt payments or questionable or corrupt transfers of property or interests may have been offered, promised, paid, or authorized by any BK Medical entity or person, or any entity or person working directly for the Company (including its affiliates and any agent or business partner), or that related false books and records have been maintained, the Company shall promptly report such conduct to the Offices. During this three-year period, the Company shall: (1) conduct an initial review and submit an initial report, and (2) conduct and prepare at least two (2) follow-up reviews and reports, as described below:

a. By no later than one (1) year from the date this Agreement is executed, the Company shall submit to the Offices a written report setting forth a complete description of its remediation efforts to date, its proposals reasonably designed to improve the Company’s internal controls, policies, and procedures for ensuring compliance with the FCPA and other applicable anti-corruption laws, and the proposed scope of the subsequent reviews. The report shall be transmitted to Chief - FCPA Unit, Fraud Section, Criminal Division, U.S. Department of Justice, 1400 New York Avenue, NW, Bond Building, Eleventh Floor, Washington, DC 20530 and Chief – Economic Crimes Unit, U.S. Attorney’s Office for the District of Massachusetts, John Joseph

Moakley U.S. Courthouse, 1 Courthouse Way, Suite 9200, Boston, MA 02210. The Company may extend the time period for issuance of the report with prior written approval of the Offices.

b. The Company shall undertake at least two (2) follow-up reviews, incorporating the Offices' views on the Company's prior reviews and reports, to further monitor and assess whether the Company's policies and procedures are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws.

c. The first follow-up review and report shall be completed by no later than one (1) year after the initial review. The second follow-up review and report shall be completed by no later than one (1) year after the completion of the preceding follow-up review. The final follow-up review and report shall be completed and delivered to the Offices no later than thirty (30) days before the end of the Term.

d. The reports will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent that the Offices determine in their sole discretion that disclosure would be in furtherance of the Offices' discharge of their duties and responsibilities or is otherwise required by law.

The Company may extend the time period for submission of any of the follow-up reports with prior written approval of the Offices.