EX-10.1 2 dex101.htm SUPPLY AGREEMENT

**Exhibit 10.1**

|  |  |
| --- | --- |
| *\*\** | *CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A CONFIDENTIAL TREATMENT REQUEST UNDER 17 C.F.R. SECTIONS 24b-2, 200.80(B)(4) AND 230.406.* |

**SUPPLY AGREEMENT**

This Agreement (the “Agreement”) effective as of the 23rd day of June, 2010 (the “Effective Date”) is by and between Kensey Nash Corporation, a Delaware corporation, (“Seller”) whose principal place of business is 735 Pennsylvania Drive, Exton, PA 19341 and St. Jude Medical, Cardiology Division, Inc. d/b/a St. Jude Medical, Cardiovascular Division a Delaware corporation, (“Buyer”), whose principal place of business is at 177 East County Road B, St. Paul, MN 55117 .

WHEREAS, Buyer desires to purchase Products (as described below) from Seller and Seller desires to sell Products to Buyer under the terms and conditions set forth herein.

NOW, THEREFORE, the parties, wishing to be legally bound, agree as follows:

1. PRODUCTS:

Collagen plugs in their current design configuration and used in currently commercially available Angio-Seal vascular closure devices (the “Collagen Plug”). Such collagen plugs are currently designated as Buyer’s Part Numbers:

|  |  |  |
| --- | --- | --- |
|  | 22934-000 | Collagen plug, Certified 5 hole, 6f STS |

|  |  |  |
| --- | --- | --- |
|  | 22935-000 | Rectangular collagen, 8f STS |

|  |  |  |
| --- | --- | --- |
|  | 23378-000 | Collagen plug, VIP, 6f plug |

|  |  |  |
| --- | --- | --- |
|  | 23378-001 | Collagen plug, VIP, 8f plug |

|  |  |  |
| --- | --- | --- |
|  | 100000973 | 6f Aus collagen plug, VIP (Australian derived) |

|  |  |  |
| --- | --- | --- |
|  | 100000974 | 8f Aus collagen plug, VIP (Australian derived) |

and, meeting the specifications (the “Specifications”) set forth in Schedule A, which is attached to and made a part of this Agreement (collectively, the “Product”). Such Specifications may be changed from time to time only as agreed to in writing by the parties.

2. DURATION: The duration of this Agreement shall be from the Effective Date until December 31, 2012 (“Initial Term”) unless terminated pursuant to the terms of this Agreement or otherwise agreed in writing by the parties. The Initial Term will be extended for one year (“Renewal Term”) unless a party provides the other party with written notice of termination on or before March 31, 2012, and such extension shall be contingent upon the parties’ agreement on Pricing with negotitation on Pricing being in good faith. Initial Term and Renewal Term may be referred to as “Term” in this Agreement.

3. CO-EXCLUSIVITY: Subject to the terms of this Agreement Seller will be, along with Buyer and/or Buyer’s affiliate(s), the co-exclusive supplier of Collagen Plugs during the Term of this Agreement.

4. QUANTITIES:

4.1 Buyer shall purchase from Seller and Seller shall sell to Buyer a minimum of \*\* units of Collagen Plugs deliverable in calendar year 2011 and a minimum of \*\* units of Collagen Plugs deliverable in calendar year 2012 (individually “Annual Minimum” or collectively “Annual Minimums”).

4.2 For Australian derived collagen plugs, Seller is not obligated to supply in excess of \*\* units per calendar year. Seller is not obligated to make more than two deliveries of Australian derived collagen per calendar year unless otherwise agreed to in writing.

5. ORDER AND DELIVERY:

5.1 Within two business days of signing of this Agreement, Buyer will issue a binding purchase order for \*\* units of Collagen Plugs deliverable on dates in 2011 as described in the purchase order (“2011 Initial Purchase Order”). The 2011 Initial Purchase Order satisfies Buyer’s Annual Minimum purchase obligation for 2011.

5.2 On or before June 30, 2011 Buyer will issue a binding purchase order for its anticipated 2012 annual needs and deliverable in 2012 (“2012 Initial Purchase Order”).

5.3 Should Buyer elect to purchase Collagen Plugs in volumes exceeding the Annual Minimum, Buyer shall issue a purchase order stating the desired shipment date(s) and the quantity being ordered. Seller shall acknowledge promptly in writing to Buyer each purchase order issued by Buyer and confirm delivery dates to destinations specified by Buyer; however, delivery dates must not conflict with Seller’s normal manufacturing lead times. Each delivery of Products shall be accompanied by Seller’s Certificate of Conformance as described more fully in the Specifications for the Products. If any terms and conditions contained in such purchase order or acknowledgment conflict with the terms of this Agreement, the terms and conditions of this Agreement shall apply to the transaction. Changes in delivery date(s) or quantity specified in a purchase order may be made by Buyer by means of a written amended purchase order, and shall become effective upon written approval by Seller.

6. ADDITIONAL QUANTITIES: During the term of this Agreement, Seller agrees to supply up to 110% of the 2011 Initial Purchase Order in calendar year 2011 and 110% of the 2012 Initial Purchase Order in 2012. In the event that Buyer requires quantities of Product exceeding the initial purchase order in 2011 and/or 2012 by greater than ten percent (10%) (“Quantity In Excess of Initial Purchase Order”) Buyer shall so notify Seller in writing at least ninety (90) days in advance of Buyer’s desired shipping date for such Quantity In Excess of Initial Purchase Order. Seller shall use commercially reasonable efforts to meet Buyer’s requirements for such Quantity In Excess of Initial Purchase Order, and shall inform Buyer within thirty (30) days of Seller’s receipt of notice whether or not Seller will supply all or a portion of such requirements. Should Seller be unable to supply Buyer with any Quantity in Excess of Initial Purchase Order, the Buyer may purchase Product from alternative suppliers only to the extent that Seller can not deliver such Quantity in excess of Initial Purchase Order, and such actions will not be a breach of any co-exclusivity provisions of this Agreement.

7. PRICE: The price for Products (the “Price”) shall be as set forth in Schedule B attached to this Agreement.

8. WARRANTY: Subject to the conditions set forth below, Seller warrants that Products shipped hereunder meets and complies with the Specifications set forth in Schedule A. Other than the foregoing, **SELLER MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE EVEN IF THAT PURPOSE IS KNOWN TO SELLER, NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY.** Buyer assumes all risk and liability for results obtained by the use of Products covered by this Agreement, whether used singly or in combination with other products.

9. INDEMNIFICATION: Subject to the conditions set forth below, Buyer shall fully indemnify Seller, and Seller’s agents, parent, subsidiaries, affiliates, employees, officers and directors, successors or assigns against all loss and expense (including, without limitation, reasonable attorney’s fees) for injury to or death of any person or loss of or damage to property incurred by Seller and resulting in any way from Buyer’s use or sale of vascular closure devices, or any act or omission, whether negligent or otherwise, on the part of the Buyer, its agents, employees, subcontractors or assignees, in connection with the performance of this Agreement except: (a) when such loss and expense are caused by a defect in any Products which were manufactured by Seller, wherein such defect caused such Products to not meet Specifications, and wherein such Product(s) were a component of a vascular closure device manufactured and sold by Buyer, or an affiliate of Buyer; or (b) when caused solely by the willful misconduct or negligence of Seller. In the event of either exception set forth in (a) or (b) in the preceding sentence, Seller shall fully indemnify Buyer, and Buyer’s agents, parent, subsidiaries, affiliates, employees, officers and directors, successors or assigns against all loss and expense (including without limitation, reasonable attorney’s fees).

The indemnifying party’s obligations under this Section shall not apply unless:

|  |  |  |
| --- | --- | --- |
|  | A. | The indemnified party gives the indemnifying party prompt written notice of claims for which the indemnified party seeks indemnification; |

|  |  |  |
| --- | --- | --- |
|  | B. | The indemnified party cooperates with the indemnifying party in the defense of such claims at the cost of the indemnifying party; |

|  |  |  |
| --- | --- | --- |
|  | C. | The indemnifying party has the sole right to defend any such claim in the manner it deems prudent, including retaining counsel of its choice; and |

|  |  |  |
| --- | --- | --- |
|  | D. | The indemnifying party shall have the sole right to settle any such claim provided that in settling any claim the indemnifying party obtains a complete release for the indemnified party and does not admit fault or liability on behalf of the indemnified party. |

10. USE OF TRADEMARK: Each party agrees that it will not, without the other party’s prior written consent, use and/or associate the other party, the other party’s corporate name or any of the other party’s trademarks, either orally or in writing, with any of the other party’s products, except that Buyer may use Seller’s name and associate Seller with Buyer’s use of Products as is required by federal or state regulation in gaining approval to market or to continue marketing any of Buyer’s devices or products.

11. CLAIMS OF NON-CONFORMITY: Buyer shall provide notice to Seller of any claim of non-conformity to Specifications arising from Products within one hundred twenty (120) days after the later of the actual or scheduled date of receipt of the shipment containing the specific Products unit that is the subject of the claim (the “Claim Period”). Except as to claims for indemnification

set forth in Section 9, failure to give notice of claim within the Claim Period, shall constitute a waiver by Buyer of all claims in respect to such Products. No claim of non-conformity to Specifications shall be allowed after Products has been processed by Buyer in any manner, except that opening the packages and inspecting Products with normal care in handling shall not constitute processing nor disallow such claim. Payment prior to inspection of Products by Buyer shall not constitute waiver of any rights under this Agreement. In addition, acknowledgement of receipt on packing slips or bills of lading shall not constitute acceptance of Products by Buyer. Products shall not be returned to Seller without Seller’s prior permission, and then only in the manner and to the destination prescribed by Seller. Seller shall reimburse Buyer for the actual costs of returning any Products returned in accordance with Seller’s instructions. Upon Seller’s confirmation of non-conformity, Seller will provide Buyer with credit, refund or replacement at Seller’s option for the non-conforming returned Products. In no event shall either party be liable to the other for special, indirect or consequential damages.

12. QUALITY CONTROL:

12.1 Inspection, Timing. All Products shall meet the Specifications contained in Schedule A, and shall be subjected to quality control inspections by Seller in accordance with Seller’s quality control standards and system which should be consistent and in conformity with the laws and regulations set forth in Section 17. If Buyer’s quality control inspection shows that any Products fails to meet the Specifications contained in Schedule A, Buyer shall notify Seller within forty-five (45) days of discovery of the non-conformity.

12.2 Lot Traceability. Vascular closure devices manufactured and sold by Buyer, or an affiliate of Buyer, shall contain lot numbers such that collagen components, including Products supplied hereunder, incorporated in such devices can be traced back to the original supplier’s lot number.

13. DELIVERIES: Deliveries shall be F.O.B. Exton, Pennsylvania, USA via standard freight carrier, using shipper of Buyer. Buyer shall be responsible for all delivery costs and will be invoiced for such by Seller. Title to and risk of loss in all Products sold hereunder shall pass to Buyer upon loading for shipment at Seller’s plant.

14. TERMS OF PAYMENT: Buyer will pay to Seller the Invoiced Price net cash thirty (30) days from date of Seller’s invoice. Seller may impose a late payment service charge of 1.5% per month on invoices not paid when due. All payments shall be in United States currency.

15. FINANCIAL RESPONSIBILITY: In the event Buyer fails to fulfill the terms of payment, or in case Seller shall have reasonable doubt at any time as to Buyer’s financial responsibility, Seller may decline to make further deliveries except upon receipt of cash or satisfactory security.

16. FORCE MAJEURE: No liability shall result from delay in performance, or nonperformance, caused by circumstances beyond the control of the party affected, including, but not limited to, Act of God, fire, flood, war, Government action, or accident. Quantities so affected may be eliminated from the Agreement without liability, but the Agreement shall remain otherwise unaffected, except that in the event Seller fails to deliver an amount to Buyer under this Section 16 following a forty-five (45) day cure period, Buyer may source Product itself or through a third party, to the extent of such failure by Seller, without breaching any exclusivity provisions of this Agreement. If Seller invokes this Section 16, any deliveries of Product subject to this Provision will be credited against the Annual Minimum. Any party claiming the benefit of this Section shall promptly so notify the other party.

17. GOVERNMENT REGULATION/APPROVALS – RESPONSES TO THIRD PARTY COMPLAINTS OR CLAIMS: Buyer shall be responsible for obtaining all necessary government approvals to market any device incorporating the Products. Seller shall manufacture Products under this Agreement in material compliance with the U.S. Quality System Regulation (QSR) and ISO 13485. Any changes to the Specifications relating to the Products must be agreed to in writing by both parties before such changes are implemented. Seller considers process validation to be a requirement of the QSR; therefore, Buyer shall either fund such required validations, subject to negotiation with Seller regarding the price and extent of validation, or provide Seller with written confirmation that Buyer will assume all responsibility for validation. Upon terms of confidentiality acceptable to Seller, Seller agrees to cooperate with Buyer in obtaining any such governmental approvals, including providing required information to the FDA or any other governmental agency requesting the information to the extent such information is readily available or can be developed at little or no cost to Seller, unless Buyer agrees to fund such information research and preparation. Similarly, Seller agrees to provide reasonable assistance, including information and data, as needed by Buyer to respond to complaints or claims asserted by third parties regarding devices incorporating the Products. If services or consulting is required to respond to issues raised by a governmental agency or in a complaint or claims asserted by a third party beyond what is customarily or reasonably provided without charge (“Supplemental Consulting”), Seller will notify Buyer of its intent to charge for Supplemental Consulting with an estimate for anticipated charges. If, after notice of Seller’s intent to charge, Buyer requests such Supplemental Consulting, Seller will charge at a rate that is discounted by twenty percent (-20%) from its regular consulting rates.

18. DOCUMENTS INCORPORATED BY REFERENCE: The following documents are hereby incorporated by reference:

A. Schedule A, entitled “Products Specifications”.

B. Schedule B, entitled “Pricing”.

19. ADVERSE EVENTS, COMPLAINTS AND EFFECTS: Buyer will investigate all adverse events, complaints and effects of which Buyer has direct or indirect knowledge, in regard to any of Buyer’s devices which incorporate Products. Buyer agrees to promptly report to Seller any such events, complaints or effects that may relate to Products. Buyer shall be responsible for all medical device reporting (MDR), vigilance reporting and/or recalls associated with any devices made or sold by Buyer which incorporate Products. Seller shall be notified in writing about any such reports or recalls that appear to relate to Products.

20. COMPLIANCE WITH LAW: Each party represents that it is and will remain in material compliance with all applicable federal, state and local laws, regulations and orders, regarding the manufacture and distribution of Products or product that incorporate Products.

21. INDEPENDENT CONTRACTOR: The employees, methods, equipment and facilities of each party shall at all times be under that party’s exclusive direction and control. Buyer’s relationship to Seller under this Agreement shall be that of an independent contractor and nothing in this Agreement shall be construed to constitute either party, or any of its employees, an agent, associate, joint venturer or partner of the other party.

22. NOTICES: All notices required hereunder shall be sent by certified mail return receipt requested, or by telex confirmed by

such certified mail, to the party to be notified at its following address or at such other address as shall have been specified in written notice from the party to be notified. If to “Seller”, addressed to: Kensey Nash Corporation, 735 Pennsylvania Drive, Exton, PA 19341, attention: Joseph W. Kaufmann. If to “Buyer”, addressed to: St. Jude Medical, Cardiology Divison, Inc. d/b/a St. Jude Medical, Cardiovascular Division 177 East County Road B, St. Paul, MN 55117, attention: Vice President Finance and Supply Chain with a copy to: Vice President and General Counsel, St. Jude Medical, Cardiovascular Division, 177 East County Road B, St. Paul, MN 55117.

23. ASSIGNMENT: This Agreement is not assignable or transferable by one party, in whole or in part, without the prior written consent of the other party, which consent shall not be unreasonably withheld, provided, however, that Buyer may assign this Agreement without Seller’s consent to an affiliate or a purchaser of all or substantially all of Buyer’s assets.

24. CLAUSE HEADINGS: The headings of clauses contained herein are used for convenience and ease of reference and shall not limit the scope or intent of the clause.

25. ENTIRETY OF AGREEMENT: This Agreement embodies the entire agreement and understanding between Seller and Buyer regarding the supply of collagen plugs for calendar years 2011 and 2012 and any extension of this Agreement beyond 2011 and 2012. The parties expressly agree that the parties’ Supply Agreement dated June 30, 2005, as amended, applies to orders for deliveries of collagen plugs in calendar year 2010 (“Prior Agreement”) and that the Prior Agreement will expire and terminate according to its terms on December 31, 2010. No amendment, modification or release from any provision hereof shall be of any force or effect unless it is in writing, signed by the parties, and specifically refers to this Agreement.

26. WAIVER: No waiver by either party or any breach of the covenants herein contained to be performed by the other party shall be construed as a waiver of any succeeding breach of the same or any other covenants or conditions hereof.

27. TERMINATION: The Agreement may be terminated by either party if:

27.1 The other party is in material breach of any material term or obligation of this Agreement and such material breach is not cured within thirty (30) days after receipt of written notice of such material breach from the terminating party, provided however, that if the nature of the breaching party’s obligations are such that more than thirty (30) days are required for cure, then such party shall not be in default if it shall have commenced performance to cure within the thirty (30) day period and thereafter diligently attempts to complete performance of cure.; or

27.2 The other party is adjudicated insolvent, has a receiver of its assets or property appointed, or files or has filed against it a petition in bankruptcy and such breach is not cured within sixty (60) days of such event; or

27.3 The other party ceases or threatens to cease to carry on all or any substantial part of its business that is relevant to this Agreement; or

27.4 The parties’ obligations pursuant to Sections 8, 9, 11, 19, 20, 28, 29 and 30 shall survive termination or expiration of this Agreement.

28. CONFIDENTIALITY: Both parties acknowledge that before and during the Term, both parties may provide or may continue to provide the other with certain proprietary and confidential information, including, without limitation, prices, data, designs, plans, drawings, technical information, trade secrets, know-how, processes, customer information, complaint analysis and

investigation, marketing strategies and competitive information (“Confidential Information”). Each agrees that it will not, during the Term, or after, for any reason, publish or disclose to any third party, except to the FDA or other competent regulatory agency, without the advance, express written authorization from the other party, any such Confidential Information, nor, except to the extent such Confidential Information is necessary in performance of this Agreement, will it use such Confidential Information.

28.1 Confidential Information does not include information which (i) is known to the receiving party prior to receipt from the disclosing party; or (ii) is or becomes public knowledge without breach of the disclosing party’s obligation; or (iii) is rightfully acquired by the disclosing party from a third party without restriction on disclosure or use; or (iv) is publicly disclosed or used following disclosing party’s receipt of written consent for such disclosure or use by an officer of the other party; or (v) disclosure is compelled by deposition, subpoena or other judicial requirement or governmental action, as evidenced by advice of legal counsel, provided that the receiving party give the disclosing party prompt advanced written notice of the Confidential Information to be disclosed as far in advance of its disclosure as is reasonably possible, practicable and legally permissible to permit the other party to obtain a protective order or take other responsive action.

28.2 The requirements of this Section terminate five (5) years after the termination or expiration of this Agreement or any renewal of this Agreement. Upon termination or expiration of this Agreement, and upon request of the other party, all materials and copies of Confidential Information shall be immediately returned to the other party, except that the receiving party may retain one archival copy in their respective legal department’s files for purposes of monitoring compliance of this Agreement, and may also retain any required documents or drawings required to be held in the Device History File or other applicable QSR or regulatory file.

29. NO PUBLICITY: Neither Buyer nor Seller will issue any press release with respect to this Agreement or any related agreements or the transactions contemplated by the parties, or otherwise make any oral or written statements or disclosures with respect to such agreements or transactions or the existence of the parties’ relationship or discussions, without the prior written consent of the other party, which consent shall not be unreasonably withheld, except to those of such party’s employees and representatives as may need to know such information for purposes of the transactions contemplated by the parties’ agreements, and except as may be required by applicable law or by obligations pursuant to any listing agreement with or rules of any national securities exchange. In the case of any such required disclosure, the disclosing party will: (1) provide the other party with written notice of the required disclosure at least forty-eight (48) hours in advance of such disclosure; and (2) limit such disclosure to the minimum required under the applicable law or obligations.

30. NON-SOLICIT/NO-HIRE: During the term of this Agreement and for a period of one (1) year thereafter, Seller and Buyer will not attempt to solicit nor directly or indirectly hire the other party’s employees or subcontractors that become known to Seller or Buyer through the performance of this Agreement.

31. CLOSED HERD: Seller shall maintain sufficient records to demonstrate that raw material has met the requirements of a Closed Herd per current ISO 22442-2 for any such source of raw material where the Products are specified by Buyer to come from a Closed Herd. Specific requirements for sourcing of Products shall be controlled by Specifications and any applicable laws or regulations.

32. COUNTERPARTS: This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

Accepted:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
| **Kensey Nash Corporation** | | |  |  |  | **St. Jude Medical, Cardiology Division, Inc.**  **d/b/a St. Jude Medical, Cardiovascular Division** | | |
|  |  | |  | |  | |  | |
| By: |  | /s/ Joseph W. Kaufmann |  |  |  |  |  |  |
| Name: |  | Joseph W. Kaufmann |  |  |  | By: |  | /s/ Brian Hansen |
| Title: |  | President & CEO |  |  |  | Name: |  | Brian Hansen |
| Date: |  | June 21, 2010 |  |  |  | Title: |  | Vice President Finance |
|  |  |  |  |  |  | Date: |  | June 23, 2010 |

**SCHEDULE A**

**PRODUCTS SPECIFICATIONS**

**Specifications follow this page.**

**\*\* [13 pages redacted]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  | **KNC** |  | **SJM** |
|  |  | |  | |
| **Initials** |  | **JWK** |  | **BH** |
|  |  | |  | |
| Date |  | 6/21/10 |  | 6/23/10 |

**SCHEDULE B**

**PRICING**

All Collagen Plug prices in the chart below are effective for orders placed for delivery in calendar years 2011 and 2012 and are for closed herd derived Product, or Australian derived Product.

**\*\* [1 page redacted]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  | **KNC** |  | **SJM** |
|  |  | |  | |
| **Initials** |  | **JWK** |  | **BH** |
|  |  | |  | |
| Date |  | 6/21/10 |  | 6/23/10 |