K082657
page 1 of 3

SECTION 7.0

OCT 17 2008

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE COLLAMEND FM IMPLANT

A. Submitter Information

Submitter's Name:	Davol Inc.
Address:	Subsidiary of C. R. Bard, Inc. 100 Crossings Boulevard Warwick, RI 02886
Telephone:	(401) 825-8583
Fax:	(401) 825-8765
Contact Person:	Kevin G. Stevens
Date of Preparation:	Friday, September 12, 2008

B. Device Name

Trade Name:	**CollaMend FM Implant**
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh

C. Predicate Device Name

Trade name: Bard CollaMend Implant (Davol, Inc.)

Trade name: SIS Hernia Repair Device (Cook Medical)

D. Device Description

The proposed device is a sterile, fenestrated, off-white sheet of lyophilized, acellular porcine dermal collagen and its constituent elastin fibers. It is processed to remove all non-collagenous cellular components and is cross-linked to increase strength and endurance. The proposed device allows cellular infiltration via fenestrations and replacement by host tissue, forming a strong repair of soft tissue defects. The proposed device will be made available in various sizes and shapes, ranging from a 4" x 6" ellipse to a 10" x 14" rectangle. The thickness of the devices will be approximately 1 mm. Surgeons will need to rehydrate the product before implanting it into the patient. The proposed device will be marketed as a sterile, single use device.

E. Intended Use

The CollaMend FM Implant is indicated to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed device and the predicate CollaMend Implant differ only in design with CollaMend FM Implant having a pre-determined pattern of holes throughout the implant to allow for a more convenient pathway for tissue ingrowth in-vivo. The fenestrations allow for cellular infiltration. The "FM" in the name CollaMend FM Implant stands for fenestrated matrix.

The proposed device follows the same current manufacturing process as the predicate CollaMend Implant until the final manufacturing step (die cutting). At this point the fenestrations are added while simultaneously the device is cut to size. All other processes before and after this manufacturing step are identical. This results in a fenestrated implant similar to the predicate SIS Hernia Repair Device (Cook Medical).

The proposed device and both predicates are manufactured from animal (porcine) tissue materials. The proposed device and predicate CollaMend Implant are manufactured from acellular porcine dermis collagen. SIS Hernia Repair Device is manufactured from porcine intestinal collagen. All three devices are flexible flat sheets of material and are available in a variety of sizes and/or shapes.

The proposed device and the predicate CollaMend Implant are lyophilized before sterilization (Ethylene Oxide). Before use, both must be completely hydrated by immersion in sterile saline solution or sterile lactated Ringer's solution for a minimum of 3 minutes or until the clinical deems appropriate for the application. SIS Hernia Repair Device requires a minimum of 10 minutes for rehydration.

G. Performance Data

Biocompatibility testing on the predicate CollaMend Implant has been completed. The biocompatibility test results show that the implant is non-toxic and non-sensitizing to biological tissues consistent with its intended use.

Given that the predicate CollaMend Implant and proposed CollaMend FM Implant are manufactured from the same source material and are identical

K082687
page 3 of 3

aside from the presence of fenestrations throughout the implant, no further biocompatibility testing was performed. The performance data provided clearly demonstrates that CollaMend FM Implant is substantially equivalent to CollaMend Implant and/or SIS Hernia Repair Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

C.R. Bard, Inc.
% Mr. Kevin G. Stevens
Sr. Regulatory Affairs Associate
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K082687
Trade/Device Name: CollaMend FM Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: September 12, 2008
Received: September 15, 2008

Dear Mr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082687

Device Name: **CollaMend FM Implant**

Indications for Use: The CollaMend FM Implant is indicated to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082687