K120728
P1/4

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary is provided per the requirements of section 807.92(c).

OCT 22 2012

Submitter Information:

Submitter's Name:	Tony John, MS Regulatory Affairs Specialist
Address:	Davol, Inc., Subsidiary of C. R. Bard, Inc. 100 Crossings Boulevard Warwick, RI 02886
Telephone:	(401) 825-8692
Fax:	(401) 825-8765

Device Name:

Trade Name:	Phasix™ Plug and Patch
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric
Classification Code:	Class II, § 878.3300, Product Code OWT (primary), OOD

Predicate Device Names:

- TephaFLEX® Mesh , K111946 and K070894 (Tepha Inc.), FDA cleared on September 26, 2011 and April 13, 2007
- Bard® PerFix™ Light Plug, K092032 (Davol Inc.), FDA cleared on December 8, 2009

Device Description:

The proposed Phasix™ Plug and Patch utilizes a fully resorbable poly-4-hydroxybutrate (P4HB) polymer material pre-formed into a three-dimensional (cone shape) configuration constructed of a fluted outer layer and multiple inner layers (petals) of mesh attached at the tip. The inner petals and cones are sewn together at the tip with a single P4HB monofilament thread. The inner petals allow the device to conform readily to defects of various sizes while the structure of the small inter-fiber pores of the P4HB mesh allows for a prompt fibroblastic response and allows tissue in-growth. The cone shape configuration of the device allows it to expand and reduce in conformation with the immediate anatomy so that the repair is tension-free. The petals can be removed to customize the Phasix Plug to each individual patient. The Phasix Plug is available in several sizes. A flat mesh onlay patch is packaged with each Phasix Plug. The onlay is also fully resorbable and is made from the same P4HB monofilament as the Phasix Plug. Unlike the plug, the onlay patch is available in only one size but is customizable.

Intended Use:

The Phasix Plug and Patch is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

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

The proposed, Phasix Plug and Patch, is similar in intended use and in technological characteristics and performance when compared to the predicate devices TephaFlex Mesh and PerFix Light Plug. All devices are intended for use in the reconstruction and repair of soft tissue deficiencies where weakness exists such as hernia repair. In addition, the proposed device and the predicate devices are similar in technological characteristics with regard to materials, design, sterilization, packaging and labeling. Where minor

technological differences exist between the proposed device and the predicate devices, performance testing demonstrates that these differences do not adversely affect the safety and effectiveness of the proposed device.

The proposed Phasix Plug and Patch device and the predicate TephaFlex Mesh are both constructed of P4HB monofilament mesh. The proposed device is constructed of P4HB monofilament mesh in a plug formation similar to the predicate Perfix Light Plug while the predicate TephaFlex Mesh is constructed of P4HB monofilament in a flat sheet formation.

The proposed Phasix Plug and Patch will have the same design as the predicate PerFix Light Plug with two modifications as described below. The first modification involves material used in the proposed device. The proposed device is made from a fully resorbable polyester mesh, P4HB, while the predicate PerFix Light Plug is made from a permanent polypropylene mesh. As discussed above this fully resorbable polyester mesh, P4HB, is identical to that used to manufacture the predicate TephaFlex Mesh. The second modification involves a reduction in the number of petals in the proposed device. Both the proposed and predicate device designs contain inner petals. However, the number of inner petals in the proposed device is less than the number of inner petals in the predicate Perfix Light Plug. In the proposed device, there are 4 inner petals in the small, medium, and large configurations and 8 inner petals in the extra large configuration. In the predicate, Perfix Light Plug, there are 8 inner petals in the small, medium, and large configurations and three medium inner cones inside one large cone in the extra-large configuration. The reduction in the number of petals in the proposed device has no impact on overall product performance as demonstrated in preclinical studies.

Similar to the predicate PerFix Light Plug, the proposed device will be packaged with a separate pre-shaped onlay patch. Additionally, both the proposed and the predicate PerFix Light Plug are packaged in the same materials, blister tray and DuPont™ Tyvek lid. All three devices undergo ethylene oxide (EtO) sterilization.

K120728
p 4/4

Performance Data:

Bench testing was performed to compare the proposed device, Phasix Plug and Patch to the predicate devices, PerFix Light Plug and TephaFlex Mesh. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" (March 2, 1999), the tests included physical characteristics including mesh weave, mesh pore size, device density, device thickness, device stiffness as well as performance evaluations including burst strength, tear resistance and suture pullout strength. In addition, preclinical studies were performed. A comprehensive study was performed in a porcine model of simulated ventral hernia repair. In the porcine model, mechanical analysis, histological analysis and molecular weight properties were assessed following implantation. An in-vivo study was performed in rats to evaluate the percentage area mesh contracture and host inflammatory/fibrotic response post-implantation. Additionally, all biocompatibility testing presented in this submission was conducted in accordance to ISO 10993-1 standards and the results indicate that the device is biocompatible per these standards.

Conclusion:

All test results provided in this submission support the safety and effectiveness of the proposed Phasix Plug and Patch device for its intended use and demonstrate that the proposed Phasix Plug and Patch device is substantially equivalent to its predicate devices, PerFix Light Plug and TephaFlex Mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C.R. Bard, Incorporated
% Mr. Tony John, MS
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 08226

OCT 2 2 2012

Re: K120728
Trade/Device Name: Phasix™ Plug and Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWT, OOD
Dated: October 03, 2012
Received: October 04, 2012

Dear Mr. John:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K120728

INDICATION FOR USE STATEMENT

510(k) Number (if known): not known

Device Name: **Phasix™ Plug and Patch**

The Phasix™ Plug and Patch is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

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)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120728