



Food and Drug Administration
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May 13, 2016

C.R. Bard, Inc.
Ms. Shweta Conner
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K153236

Trade/Device Name: Small PerFix Light Plug with 6 x 13.5 cm HydroLight onlay,
Medium PerFix Light Plug with 6 x 13.5 cm HydroLight onlay,
Large PerFix Light Plug with 6 x 13.5 cm HydroLight onlay,
Extra Large PerFix Light Plug with 6 x 13.5 cm HydroLight onlay

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical Mesh

Regulatory Class: Class II

Product Code: FTL

Dated: April 12, 2016

Received: April 13, 2016

Dear Ms. Conner:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153236

Device Name

PerFix™ Light Plug with HydroLight™ Onlay

Indications for Use (Describe)

The PerFix™ Light Plug with HydroLight™ Onlay is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 510(k) Summary

I. SUBMITTER

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Date Prepared: May 11, 2016

II. DEVICE

Name of Device: PerFix™ Light Plug with HydroLight™ Onlay
510(k) number: K153236
Product Code 0117450, 0117460, 0117470, 0117480
Common or Usual Name: Mesh, Surgical, Polymeric/ Surgical Mesh
Classification Name: 21 CFR §878.3300 – Surgical Mesh
Regulatory Class: II
Product Code: FTL

III. PREDICATE DEVICE

The predicate device for this submission is the BARD® PerFix™ Light Plug, cleared in K092032, marketed by Davol Inc., a subsidiary of CR Bard, Inc. This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The PerFix™ Light Plug with HydroLight™ Onlay (also referenced as “PerFix™ Light Plug HL” and “PerFix™ Light HL” in the submission) is a permanent, tissue contacting implant.

The PerFix™ Light Plug with HydroLight™ Onlay is comprised of two components: the BARD® PerFix™ Light Plug (hereon referred to as “plug”) cleared in K092032; and the onlay, a Lightweight Large Pore Mesh (LLPM) with HydroLight™ hydrogel technology. The HydroLight™ hydrogel coating is a 90:1 mixture of polyvinylpyrrolidone (PVP) and polyethylene glycol (PEG).

V. INDICATIONS FOR USE

The PerFix™ Light Plug with HydroLight™ Onlay is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

The Indications for Use statement for the subject PerFix™ Light Plug with HydroLight™ Onlay is identical to that of the predicate BARD® PerFix™ Light Plug.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 5-1: Device Substantial Equivalence – General Characteristics

Device Features		Subject device PerFix™ Light Plug with HydroLight™ Onlay	Predicate device BARD® PerFix™ Light Plug (K092032)
Indications for Use		<i>Identical to predicate device:</i> Indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.	Indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.
Device Sterilization		<i>Identical to predicate device:</i> ETO SAL 10 ⁻⁶	ETO SAL 10 ⁻⁶
Plug Material		<i>Identical to predicate device:</i> Co-knitted using polypropylene	Co-knitted using polypropylene
Onlay Material		Co-knitted using polypropylene Hydrogel coating- Blend of polyvinylpyrrolidone (PVP) and polyethylene glycol (PEG)	Co-knitted using polypropylene No coating
Shape of Plug		<i>Identical to predicate device:</i> Pre-formed cone shape Available sizes- small, medium, large and extra large	Pre-formed cone shape Available sizes- small, medium, large and extra large
Shape of Onlay		Flat pre-shaped mesh with key hole Available size- 6 x 13.5 cm	Flat pre-shaped mesh with no keyhole Available size- 5.8 x 13.7 cm
Packaging	Plug	<i>Identical to predicate device:</i> Blister tray with Tyvek lid	Blister tray with Tyvek lid
	Onlay	Tyvek/Mylar pouch in blister tray with Tyvek lid	Blister tray with Tyvek lid

VII. PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination.

Performance standards

No performance standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Biocompatibility testing

The biocompatibility evaluation for the PerFix™ Light Plug with HydroLight™ Onlay was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “*Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’*” May 1, 1995; and International Standard ISO 10993-1 “*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,*” as recognized by FDA. The following tests were conducted and the results indicate that the subject device is biocompatible per the referenced standards:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Implantation: Subcutaneous Implantation (4 week)
- Implantation: Subcutaneous Implantation (8 week)
- Implantation: Subcutaneous Implantation (13 week)
- Toxicological Assessment

Electrical safety and electromagnetic compatibility (EMC)

The subject PerFix™ Light Plug with HydroLight™ Onlay is not an electro-mechanical medical device nor is it a medical system; therefore this section does not apply.

Software Verification and Validation Testing

The subject PerFix™ Light Plug with HydroLight™ Onlay does not contain software; therefore this section does not apply.

Performance Testing

Performance testing was completed for the subject PerFix™ Light Plug with HydroLight™ and predicate BARD® PerFix™ Light Plug. In accordance with FDA’s “Guidance for the

Preparation of a Premarket Notification Application for a Surgical Mesh” published March 2, 1999, testing included the following physical and performance characteristic evaluations.

Bench Testing:

- Mesh Thickness
- Mesh Weave Characteristics
- Monofilament Diameter
- Pore Size
- Device Weight
- Mesh Density (Linear)
- Tensile Strength
- Device Stiffness
- Suture Pull Out Strength
- Burst Strength
- Tear Resistance
- Material Interaction Testing

All samples tested met the established acceptance criteria. The PerFix™ Light Plug component of the subject device is identical to that of the predicate BARD® PerFix™ Light Plug (K092032). For the HydroLight™ Onlay which is the only difference between the subject and the predicate, performance testing demonstrates that the Onlay component does not adversely affect the safety and effectiveness of the proposed device. The subject PerFix™ Light Plug with HydroLight™ Onlay passed all test requirements and demonstrated substantial equivalence to the test results of the predicate device.

Animal Study:

The performance of the subject PerFix™ Light Plug with HydroLight™ Onlay was evaluated by animal study.

The following *in-vivo* animal studies were conducted:

- **Histological Characterization Comprehensive Rat GLP Study** to histologically evaluate the host inflammatory/fibrotic response, and the presence or absence of hydrogel coating following subcutaneous implantation over a simulated abdominal surgical defect in the rat.
- **Acute GLP Porcine Study** to determine tissue plane conformance and positioning aid properties following placement in the subcutaneous muscular abdominal tissue plane in the porcine model.

All samples tested met the established acceptance criteria and demonstrated substantial equivalence to the test results of the predicate device.

Clinical Studies

Clinical studies were not performed for either the subject or the predicate device, however, the following clinical data was included to support the safety and effectiveness and demonstrate substantial equivalence to the predicate BARD® PerFix™ Light Plug (K092032)

- Champault G, Torcivia A, Paolino L, Chaddad W, Lacaine F, Barrat C. A self-adhering mesh for inguinal hernia repair: preliminary results of a prospective, multicenter study. *Hernia*. 2011;15(6):635-41.
- Tollens T, Kennes J, Vermeiren K, Aelvoet C. Prospective, Single Center, Single Surgeon's Experience with an Atraumatic Self-Adhering Mesh in 100 Consecutive Patients. *Surgical Technology Int*. 2014;(24):178-82.
- Adhesix™ Intraoperative Handling Characteristics Data from EU Clinical Experience
- Testimonial of Dr. Keith Millikan, MD FACS, Surgeon & Professor, Rush University.
 - Based on his preclinical evaluation on the usability, interoperability, and clinical utility of the coating.
 - VIDEO 1 – “Millikan Preclinical Lab – Trimming” (1:26s)
 - VIDEO 2 – “Millikan Preclinical Lab – Mesh Manipulation” (0:45s)
- Testimonial from Dr. Timothy Tollens, MD.

VIII. CONCLUSIONS

The comparative analysis, performance testing results and clinical data demonstrate the subject PerFix™ Light Plug with HydroLight™ Onlay is substantially equivalent to the currently marketed predicate BARD® PerFix™ Light Plug (K092032).