



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

May 31, 2016

C.R. Bard Inc.
Mr. Andrew Harrell
Senior Regulatory Affairs Specialist
100 Crossings Blvd
Warwick, Rhode Island 02886

Re: K160900

Trade/Device Name: Capsure Fixation System - Straight 5mm X 37 Cm - 30 Permanent Fasteners, Capsure Fixation System - Straight 5mm X 37 Cm - 15 Permanent Fasteners

Regulation Number: 21 CFR 878.4750

Regulation Name: Implantable Staple

Regulatory Class: Class II

Product Code: GDW

Dated: March 31, 2016

Received: April 1, 2016

Dear Mr. Harrell:

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,

Jennifer R. Stevenson -A

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: K160900

Device Name: CapSure™ Permanent Fixation System

The CapSure™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

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)
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Section 5 510(k) Summary

SUBMITTER

Davol Inc.
100 Crossings Boulevard
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Date Prepared: March 31, 2016

II. DEVICE

Name of Device: CapSure™ Permanent Fixation System (product code GDW)
Common Name: Implantable Staple
Classification Name: Implantable staple (21 CFR §878.4750)
Regulatory Class: II
Product Code: GDW

III. PREDICATE DEVICE

K142808 CapSure™ Permanent Fixation System (Davol Inc.) – Cleared March 9, 2015

IV. DEVICE DESCRIPTION

The CapSure™ Permanent Fixation System is a sterile single use device that delivers either 15 or 30 permanent fasteners via a straight shaft. The shaft of the CapSure™ Permanent Fixation System is 37 cm in length. The fasteners are designed with a 316L Stainless steel helical coil and polyetheretherketone (PEEK) cap on the proximal end to support mesh or tissue.

V. INDICATIONS FOR USE

The CapSure™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

The Indications for Use statement for the subject device is unchanged as a result of this 510(k) and remains identical to the device cleared in K142808. Both the subject and predicate devices retain the identical intended use for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

| Device Comparison | | |
|---|------------------------------|---|
| Device Features | CapSure™ (Subject Device) | CapSure™ (Predicate – K142808) |
| <i>Intended Use</i> | Identical to predicate | Permanent soft tissue fixation |
| <i>Indication For use</i> | Identical to predicate | Indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair. |
| <i>Mesh/Tissue Retention Feature Material</i> | Identical to predicate | Polyetheretherketone (PEEK) cap (injection molded) |
| <i>Fastener Material</i> | Identical to predicate | 316L Stainless Steel (metal wire fabrication) |
| <i>Fastener Body Contact</i> | Identical to predicate | Long term implant (>30 days) contacting tissue and/or bone |
| <i>Fastener Shape/Design</i> | Identical to predicate | Helical Coil/Screw with retention feature (proximal cap) |
| <i>Fastener Dimensions</i> | Identical to predicate | 4.2 mm overall fastener length 4.0 mm overall cap diameter |
| <i>Fastener Quantity per Device</i> | Identical to predicate | 15 & 30 fasteners |
| <i>Deployment component –Shaft Length</i> | Identical to predicate | 37 cm length |
| <i>Deployment component Handle design</i> | Identical to predicate | Handle actuated-level delivery device |
| <i>Fastener Delivery System</i> | Identical to predicate | Rotational – driven by inner shaft assembly |
| <i>Device Sterilization</i> | Identical to predicate | EtO |

VII. PERFORMANCE DATA

Performance Standards

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

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

Biocompatibility testing

The biocompatibility evaluation for the CapSure™ Permanent Fixation System was reported in K142808, 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 battery of testing included the following tests:

Device Testing

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogen Testing

Implant Materials Testing

- Cytotoxicity
- Maximization Sensitization Study
- Intracutaneous Study
- Acute Systemic Toxicity Study
- Pyrogenicity
- Hemolysis
- Complement Activation Assay
- Intramuscular Implant – 12 Weeks
- Rabbit Femoral Bone Implant – 12 Weeks
- Rabbit Femoral Bone Implant – 26 Weeks
- Bacterial Reverse Mutation (Ames) Assay
- In Vitro Mouse Lymphoma Mutation Assay
- Mouse Peripheral Blood Micronucleus Test
- Subacute (14-Day) Intraperitoneal Toxicity Study Mice
- Subchronic (14-Day) Intravenous Toxicity Study Mice
- Subchronic (13-Week) Toxicity Study in Rats
- In Vivo Neurotoxicity
- Non-Volatile Residue
- Residue on Ignition
- Turbidity
- UV Absorption

The deployment device of the CapSure™ Permanent Fixation System is determined to be tissue contacting for duration of less than 24 hours, while the fasteners are determined to be permanent implants. The implantable fastener material conforms to ASTM F138 (316L Stainless Steel) and ASTM F2026 (PEEK).

All samples tested met the acceptance criteria.

Mechanical testing

The following non-clinical tests were completed for the CapSure™ Permanent Fixation System in K142808 and passed all the test requirements and showed substantial equivalence to the results of the predicate device identified in K142808 – ProTack™.

- Trigger Force
- Mesh Compatibility
- Deployment Reliability

- MR Compatibility
- Burst Testing

All samples tested met the acceptance criteria.

Animal Studies

The following *in vivo* study was completed for this premarket submission

- Porcine implantation study

As compared to the control, CapSure™ had significantly ($p < 0.05$) fewer tissue attachments to fasteners, indicative of a role of the CapSure™ Device in minimizing tissue attachments to fasteners.

Clinical Studies

Clinical studies were not performed for this device nor were clinical studies performed for the predicate device, as they are not necessary to adequately assess the safety and effectiveness of Class II products.

VIII. CONCLUSIONS

The CapSure™ Permanent Fixation System is substantially equivalent to the legally marketed predicate device for the following reasons:

- A) The intended use and indications for use are not changed from the predicate device.
- B) No technological characteristics have changed related to this premarket notification.
- C) The update to the instructions for use has been supported by adequate performance data.

As demonstrated in the completed tests that were conducted by the company in K142808 and this submission, the CapSure™ Permanent Fixation System is substantially equivalent to the legally marketed predicate device.