

AUG 11 2005

Premarket Notification for the Salute® II Disposable Fixation Device

7.0 510(k) Summary of Safety and Effectiveness:

A. Submitter Information:

Submitter's Name: Davol, Inc.
 Address: Subsidiary of C. R. Bard, Inc.
 100 Sockanossett Crossroad
 Cranston, RI 02920

Telephone: 401-463-7000 Ext. 2386
 Fax: 401-463-3845
 Contact Person: Lucinda L. Fox

B. Device Name: Salute II Disposable Fixation Device

C. Predicate Device Name: Salute Stapler and Staples
(Onux Medical, Inc.)

D. Device Description:

The **Salute** II Disposable Fixation Device consists of a handle, shaft/shaft tip and comes preloaded with 316L stainless steel wire. The device is used to deliver permanently implanted Q-shaped constructs (Q-Rings). Depending on user preference, the device is offered in an 18cm shaft preloaded with either 10 or 30 Q-Rings and a 38cm shaft (fits into a 5mm trocar) preloaded with either 10, 30, or 60 Q-Rings.

E. Intended Use:

The **Salute** II Disposable Fixation Device is indicated for use in a variety of laparoscopic/endoscopic or open surgical procedures for fixation of prosthetic material and approximation of tissue.

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

The Proposed and Predicate Products are designed to place stainless steel wire into tissue/prosthetics to fixate prosthetics/approximate tissue. Both consist of a handle and shaft, which are used to deliver permanently implanted, 316L stainless steel Q-shaped constructs (Q-rings). The key differences between the Proposed and Predicate Products are: number of Q-rings delivered; disposable instead of reusable; preloaded with 316L stainless steel wire instead of a separate implant cartridge. In addition, the Proposed Product includes some features (distal tip rotation, end of construct indication, and handle lock-out when the wire is depleted) not available in the currently marketed Predicate Product. The new features were added as user conveniences based on market and user feedback.

G. Performance Data

Based on bench testing, the Proposed Product delivers the same shape and comparably sized Q-rings, which provides equivalent fixation. In addition, biocompatibility will be completed and passed before the Proposed Product is launched. Therefore, based on bench testing and biocompatibility, the Proposed Product will be safe and effective for its intended use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lucinda L. Fox
Manager, International
Regulatory & Clinical Affairs
Daval, Inc.
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K051848
Trade/Device Name: Salute[®] II Disposable Fixation Device
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: July 5, 2005
Received: July 7, 2005

Dear Ms. Fox:

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.

Page 2- Ms. Lucinda L. Fox

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a small "for" written below the name.

Mark N. Melkerson
Acting 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): K051848

Device Name: Salute® II Disposable Fixation Device

Indications For Use:

The Salute® II Disposable Fixation Device is indicated for use in a variety of laparoscopic/endoscopic or open surgical procedures for fixation of prosthetic material and approximation of tissue.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Barbara Buchwald for Melkerson
(Division Sign-Off) Page 1 of 1
Division of General, Restorative
and Neurological Devices

510(k) Number K051848