K093661

1 of 2

510(k) SUMMARY

FEB 10 2011

NiTi Surgical Solution'
ColonRing™ Device

Submitter's Name:

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Date Prepared:

November 19, 2009

Trade Name:

ColonRing™ Device

Classification Name:

Implantable Clip, FZP

Predicate Devices

Compression Anastomosis Ring (CAR™) (NiTi Surgical Solutions Ltd.), cleared under K062008 and K050356

Intended Use

The NiTi ColonRing™ device is intended for use throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses, in both open and laparoscopic surgeries. Once wound strength is sufficient to maintain the anastomosis, the NiTi ColonRing™ is passed from the body.

Technological Characteristics

The ColonRing™ device is a sterile single use device. The ColonRing™ provides a simple method for the creation circular compression anastomosis of the alimentary tract. After a period of 7-10 days, a compression-induced necrosis of the tissue sides underneath the ring occurs and the whole device, together with the necrosed tissue that was compressed by the rings, detaches and is naturally expelled with the stool.

Substantial Equivalence and Performance Data

The ColonRing™ has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate device. The minor differences in the ColonRing™ technological characteristics do not raise any new questions of safety or effectiveness. Performance data including bench tests and animal data demonstrates that the ColonRing™ is as safe and effective as its predicate device. Based on the design verification and validation processes, performed as a result of risk analysis, NiTi Surgical Solutions Ltd. believes that the ColonRing™ is substantially equivalent to its predicate device.

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

NiTi Surgical Solutions, Ltd.
% Hogan and Hartson, L.L.P.
Jonathan Kahan, Esq.
555 Thirteenth Street, NW
Washington, District of Columbia 20004-1109

FEB 10 2011

Re: K093661
Trade/Device Name: ColonRing™ Device
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: January 31, 2011
Received: January 31, 2011

Dear Mr. Kahan:

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

Indications for Use Statement

510(k) Number (if known): K093661

Device Name:

Indications for Use:

The NiTi ColonRing™ device is intended for use throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses, in both open and laparoscopic surgeries. Once wound strength is sufficient to maintain the anastomosis, the NiTi ColonRing™ is passed from the body.

Prescription Use X AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 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 MXM

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

510(k) Number K093661