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510(K) SUMMARY

JUN 1 2 2013

This 510(k) Summary is being submitted in accordance with requirements of 21 CFR 807.92.

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Date Prepared: 4/19/2013

Device Name: MINT™

Trade Name: MINT™
Classification Name: Suture, Surgical, Absorbable, Polydioxanone
Common Name: Absorbable polydioxanone surgical suture
Classification: Class II
Product Code: NEW
Regulation number: 21 CFR 878.4840

General description

The MINT™ synthetic absorbable PDO suture is made of polydioxanone. Polydioxanone has been found to be nonantigenic and to elicit only a slight tissue reaction during absorption. The pigment for the violet dye is D&C Violet No.2. The MINT™ is available sterile after ethylene oxide (EO) gas sterilization and degrades or dissolves over time in tissue.

Each dyed (violet) suture has bi-directional barbs along the long axis of the suture monofilament without needle attachment. The MINT™ Synthetic Absorbable PDO suture approximate tissues, without the need to tie surgical knots, by using the opposing barbs on the suture surface to embed in the tissues after the surgeon precisely places the suture within the tissues.

While the formation of barbs in the MINT™ reduces the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduce their effective strength. For this reason, the strength of the MINT™ can be compared with USP knot strength of non-barbed sutures and the USP size of MINT™ is 1 while its tensile strength is equivalent to that of USP 2-0.

Intended uses

The MINT™ comprised of PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

Predicate device

- Quill™ Self-Retaining System (SRS) comprised of PDO(Polydioxanone), Angiotech (Quill Medical, Inc) (K080985)
- Quill™ Synthetic Absorbable Barbed Suture, Angiotech (Quill Medical, Inc) (K042075)

Safety and performance

Testing was performed per *FDA's Class II Special Controls Guidance Document: Surgical Sutures*, including testing in accordance with the USP monograph for absorbable sutures, in vitro and in vivo resorption testing, biocompatibility testing in accordance with ISO 10993, and a barb holding strength evaluation.

Substantial equivalence summary

The MINT™ has a substantially equivalent intended use as the identified predicate, Quill™ Self-Retaining System (SRS) comprised of PDO (Polydioxanone) manufactured by Angiotech and is made of polydioxanone intended for soft tissue approximation. The subject and predicate devices are composed of the same material (PDO), have bi-directional barbs, and have the same indications for use. The subject device differs from the predicate with respect to barb size and spacing.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Quill™ Self-Retaining System (SRS) comprised of PDO(Polydioxanone) (K080985) concludes that the MINT™ is substantially equivalent to predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 12, 2013

HansBiomed Corporation
% KoDent, Inc.
Ms. April Lee
325 N. Puente Street, Unit B
Brea, California 92821

Re: K130191
Trade/Device Name: MINT™
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: May 08, 2013
Received: May 10, 2013

Dear Ms. Lee:

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,

David Krause -S

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

Enclosure

5. INDICATIONS FOR USE

510(k) Number (if known): K130191

Device Name: MINT™

Indications for Use:

The MINT™ comprised of PDO is indicated for use in soft tissue approximation where use of an absorbable suture is appropriate.

Prescription Use ___X____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130191