K092590 page 1/2

510(k) SUMMARY
Ethicon, Inc.
PDS* Flexible Plate

FEB 17 2010

Submitter's Name, Address, Telephone Number:

Ethicon, Inc., Ethicon Products
Route 22 West
P.O. Box 151
Somerville, NJ 08876-0151

Phone: (908) 218-3275
Facsimile: (908) 218-2595

Date Prepared:

Date Prepared: August 21th, 2009

Contact Person:

Leslie Young
Sr. Regulatory Specialist

Trade Name of Device and Name/Address of Sponsor:

PDS* Flexible Plate
Ethicon, Inc.
Route 22 West
P.O. Box 151
Somerville, NJ 08876

Common or Usual Name:

Polymer, ear, nose and throat, synthetic, absorbable

Classification Name:

Polymer, ear, nose and throat, synthetic, absorbable ; 21 CFR § 874.3620

Classification Code:

NHB; Class II

* Trademark of Ethicon, Inc.

Predicate Devices:

Ethicon Endo-Surgery's Orthosorb Pin (K901456)

Ethicon's PDS* Suture (N18331)

Macropore Biosurgery, Inc.'s MACROPORE ENT Reconstruction Film (K012769)

LactoSorb Sheets (K992158)

Silmax Sheeting (K954382)

Intended Use / Indications for Use

Indicated for:

– Nasal soft-tissue and cartilage reconstruction

Technological Characteristics

PDS Flexible Plate are made of poly-p-dioxanone, an aliphatic polyester which is manufactured by polymerisation of the monomer p-dioxanone. PDS Flexible Plate are dyed with D+C violet # 2 (Color index Number 60725). PDS Flexible Plate are available in various film thicknesses, some of which are also perforated. PDS Flexible Plate can be trimmed to suit the anatomical conditions. The PDS Flexible Plate is a sterile, single use device.

Performance Data

PDS Flexible Plate underwent an extensive performance testing program to support that the PDS Flexible Plate fulfill the device requirements as defined in user specifications, function as intended, and are substantially equivalent to the predicate devices. Bench top testing compared the device to predicate devices in thickness, tensile properties and flexibility and was shown to have comparable characteristics. Preclinical evaluations with the device and its predicates demonstrate the device's ability to achieve the intended use and support substantial equivalence.

Substantial Equivalence

The PDS Flexible Plate has the same intended use, and similar indications for use, technological characteristics, and principles of operation as its predicate devices. The technological differences between the PDS Flexible Plate and the predicate devices raise no new issues of safety or effectiveness. Performance data and preclinical evaluations demonstrate that the device is as safe and effective as the predicate devices for the stated use. Thus, the PDS Flexible Plates are substantially equivalent

* Trademark of Ethicon, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 17 2010

Ethicon, Inc.
% Ms. Leslie Young
Senior Regulatory Specialist
Route 22 West
P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K092590
Trade/Device Name: PDS™ Flexible Plate
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose and throat synthetic polymer material
Regulatory Class: Class II
Product Code: NHB
Dated: January 18, 2010
Received: January 19, 2010

Dear Ms. Young:

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): K092590
Device Name: PDS* Flexible Plates
Indications for Use:

The Ethicon Inc. PDS Flexible Plates are indicated for:

– Nasal soft-tissue and cartilage reconstruction

* Trademark of Ethicon, Inc.

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)

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

510(k) Number K092590