JUN 20 2011

# 510(k) Summary

**June 15, 2011**

**Cook Biotech Incorporated**

**Biodesign® Nipple Reconstruction Cylinder**

Manufacturer Name: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906
Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name: | Biodesign Nipple Reconstruction Cylinder |
| Common Name: | Surgical Mesh |
| Classification Regulations: | Class II, 21 CFR §878.3300 (FTM) |

INTENDED USE:

The Biodesign Nipple Reconstruction Cylinder is intended for implantation to reinforce soft tissue where weakness exists, in plastic and reconstructive surgery of the nipple. The cylinder is supplied sterile and is intended for one-time use.

DEVICE DESCRIPTION:

The Biodesign Nipple Reconstruction Cylinder is composed of a bioabsorbable, extracellular collagen matrix (Small Intestinal Submucosa, SIS). The SIS material is identical to the predicates SurgiSIS® Mesh (K980431, K062696), SIS Plastic Surgery Matrix (K034039), and SIS Facial Implant (K050246, K070738) all manufactured by Cook Biotech Incorporated. The Biodesign Nipple Reconstruction Cylinder is a rolled SIS mesh and available in sizes from 0.7 cm to 1.0 cm in diameter and 1.0 cm to 2.5 cm in length. The cylinder is a scaffold which becomes infiltrated by the host cells during the body's natural repair process. The device is implanted using a skin flap procedure that prevents migration of the device. A PET marking template (Class I, 21 CFR 888.4800) and silicone (35A durometer) nipple shield (Class I, 21 CFR 880.5630 ) to be placed over the cylinder post-operatively, are included with the device. The use of the Biodesign Nipple Recosntruction Cylinder, an off-the-shelf graft, is advantageous in that a donor site is no longer necessary.

The Biodesign Nipple Reconstruction Cylinder is identical to its predicates in terms of material (SIS), its rolled design (SurgiSIS, SIS Facial Implant [K070738]) and technology (its ability to be incorporated into the body). The device is packaged in a lyophilized (dried) state and supplied sterile in a sealed double pouch system.

EQUIVALENCE TO MARKETED DEVICES

The Biodesign Nipple Reconstruction Cylinder is similar with respect to intended use, and identical with respect to materials and technological characteristics to the predicate devices in terms of section 510(k) substantial equivalence, as shown through bench (suture retention strength and ultimate tensile strength), animal, and biocompatibility testing (conducted in accordance to ISO 10993-1 standards) and clinical testing.

**Bench testing**

The following mechanical tests were performed on finished, terminally sterilized SurgiSIS® mesh that comprise the Biodesign Nipple Reconstruction Cylinder:

- Suture retention strength
- Ultimate tensile strength

The tests provided evidence that the Biodesign Nipple Reconstruction Cylinder performed similarly to its predicate devices.

**Biocompatibility testing**

The following biocompatibility tests were performed on sterilized SurgiSIS Mesh, which is identical in composition to the Biodesign Nipple Reconstruction Cylinder (according to the ISO 10993-1 standard):

- Genotoxicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- ISO Sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic systemic toxicity

The results of these tests provided evidence that the Biodesign Nipple Reconstruction Cylinder meets biocompatibility requirements of the ISO standard.

**Animal testing**

An animal study using finished devices of SIS, the same material that comprises the Biodesign Nipple Reconstruction Cylinder, in a guinea pig model showed that the

device performed adequately with minimal inflammation and provided increased soft tissue volume at 5 months.

**Clinical Testing**

The clinical performance of the Biodesign Nipple Reconstruction Cylinder was assessed in 2 case studies and anecdotal evidence of 186 device implants. Of the 188 implants, complications included device extrusion (number of extrusions not given). Follow-up periods ranged from 2 to 12 months. The clinical studies showed the Biodesign Nipple Reconstruction Cylinder as substantially equivalent to its predicates in its application.

**Substantial Equivalence**

See Table 1 for a comparison of the subject device and its predicates.

Table 1 – Substantial Equivalence Comparison

| Device | Biodesign Nipple Reconstruction Cylinder | SurgiSIS® Mesh | SIS Plastic Surgery Matrix | SIS Facial Implant |
|---|---|---|---|---|
| Manufacturer | Cook Biotech Incorporated | Cook Biotech Incorporated | Cook Biotech Incorporated | Cook Biotech Incorporated |
| 510(k) Number | Not assigned | K980431 | K034039 | K050246, K070738 |
| Intended Use | For implantation to reinforce soft tissue, where weakness exists, in plastic and reconstructive surgery of the nipple. | For implantation to reinforce soft tissue. | For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair in plastic and reconstructive surgery. | For use to provide soft tissue repair or reinforcement in plastic and reconstructive surgery of the face and head. |
| Material | Small intestinal submucosa Primarily Types I, III, IV and VI collagen | Small intestinal submucosa Primarily Types I, III, IV and VI collagen | Small intestinal submucosa Primarily Types I, III, IV and VI collagen | Small intestinal submucosa Primarily Types I, III, IV and VI collagen |
| Dimensions | 0.7 cm to 1.0 cm diameter 1.0 cm to 2.5 cm length | 2 x 4 cm to 20 x 40 cm | 0.2 cm to 7 cm x 20 cm length | 1.5 to 7 mm diameter 5-15 cm length |
| Thickness | 0.7 cm to 1.0 cm | 100 µm -1500 µm | 0.1 mm to 1.5 mm | 1.5 mm to 7 mm |

CONCLUSION: The pre-clinical, animal and clinical tests performed on the Biodesign Nipple Reconstruction Cylinder show that the device is substantially equivalent to its predicates.

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

Cook BioTech, Inc.
% Mr. Perry W. Guinn
VP, Quality Assurance and Regulatory Affairs
1425 Innovation Place
West Lafayette, Indiana 47906-1000

JUN 20 2011

Re: K110402
Trade/Device Name: Biodesign® Nipple Reconstruction Cylinder
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: June 9, 2011
Received: June 10, 2011

Dear Mr. Guinn:

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,

for Peter Rumm via mm

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

DSRD + CDRH DSRD Rumm

Enclosure

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# Indications for Use

510(k) Number (if known):

Device Name: **Biodesign® Nipple Reconstruction Cylinder**

Indications For Use:

**The Biodesign Nipple Reconstruction Cylinder is intended for implantation to reinforce soft tissue in plastic and reconstructive surgery of the nipple. The cylinder is supplied sterile and is intended for one-time use.**

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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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David Krause for MKM

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

510(k) Number K110402