JUN 3 0 2004

POREX
SURGICAL PRODUCTS GROUP

510(k) SUMMARY
(Amended May 19, 2004)

Manufacturer and Submitter

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

Contact: Greg Swords
e-mail: greg.swords@porex.com

Date: February 9, 2004

Trade Name: MEDPOR Craniofacial Implants with Embedded Titanium Mesh

Class II Device
510(k) Number K040364

Substantially equivalent to:

A. MEDPOR® Surgical Implant Material
B. MEDPOR® Barrier Implants
C. MEDPOR® Barrier Channel Implants
D. Other titanium bone meshes currently marketed

Device description:

This device is a MEDPOR/titanium mesh craniofacial implant available in three configurations: (1) A titanium mesh encapsulated within a thin coating of solid high density polyethylene. (2) A titanium mesh encapsulated within a MEDPOR Biomaterial porous polyethylene sheet with a nonporous barrier on one side. (3) A titanium mesh encapsulated within a MEDPOR Biomaterial porous polyethylene sheet.

Indications for Use:

MEDPOR Biomaterial with Embedded Titanium Mesh Implants are intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Mr. Greg Swords
VP, Technology and Development
Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265-1017

Re: K040364
Trade/Device Name: MEDPOR® Craniofacial Implants with Embedded Titanium Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, FTL
Dated: February 9, 2004
Received: February 13, 2004

Dear Mr. Swords:

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.
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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

POREX
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INDICATION FOR USE
(Amended May 19, 2004)

Applicant: Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

510(k) Number: K 040364

Device Name: MEDPOR Craniofacial Implants with Embedded Titanium Mesh

Indications for Use:

MEDPOR Biomaterial with Embedded Titanium Mesh Implants are intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040364

Prescription Use: X OR Over the Counter Use: _____