K072207
CONFIDENTIAL
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DuraGen XS™ *Dural Regeneration Matrix*
510(k) Summary

Submitter's name and address:
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536 USA

AUG 2 3 2007

Contact person and telephone number:
Peter Allan
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536
(609) 936- 2237

Date prepared: August 7, 2007

Name of device:
Proprietary Name: DuraGen XS™ *Dural Regeneration Matrix*
Common Name: Dural Graft Matrix
Classification Name: Dura Substitute

Substantial Equivalence:
The DuraGen XS™ *Dural Regeneration Matrix* is substantially equivalent in function and intended use to the currently marketed DuraGen Plus® *Dural Regeneration Matrix* (K032693).

Intended Use:
DuraGen XS™ *Dural Regeneration Matrix* is indicated as a dura substitute for the repair of dura mater.

Device Description:
DuraGen XS™ *Dural Regeneration Matrix* is an absorbable implant for repair of dural defects and is to be used as sutureless onlay graft. DuraGen XS™ *Dural Regeneration Matrix* is an easy to handle, soft, white, pliable, nonfriable, porous collagen matrix with increased mass and density. DuraGen XS™ *Dural Regeneration Matrix* is supplied sterile, nonpyrogenic, for single use in double peel packages in a variety of sizes.

Conclusion:
Valid scientific evidence through physical property testing provides reasonable assurance that DuraGen XS™ *Dural Regeneration Matrix* is safe and effective under the proposed conditions of use, and is, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra LifeSciences Corporation
% Mr. Peter Allan
Regulatory Affairs Project
Manager
311 Enterprise Drive
Plainsboro, New Jersey 08536

AUG 2 3 2007

Re: K072207
Trade/Device Name: DuraGen XS™ *Dural Regeneration Matrix*
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura substitute
Regulatory Class: II
Product Code: GXP
Dated: August 7, 2007
Received: August 8, 2007

Dear Mr. Allan:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: DuraGen XS™ *Dural Regeneration Matrix*

Indications For Use:

DuraGen XS™ *Dural Regeneration Matrix* is indicated as a dura substitute for the repair of dura mater.

Prescription Use _X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k 071269