JUL 27 2004

K041000

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510(k) Summary

This 510(k) summary for Durepair® Dura Regeneration Matrix is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by:

Medtronic Neurosurgery
125 Cremona Drive
Goleta, CA 93117

Contact Person:

Jeffrey Henderson
Vice President, Quality & Regulatory Affairs
Tel: (805) 968-1546 Ext. 1770 or 1-800-826-5603
Fax: (805) 968-9336

Date Prepared:

April 16, 2004

Device Information:

Proprietary name:	Durepair® Dura Regeneration Matrix
Classification name:	Dura substitute
Device classification:	Class II (21CFR882.5910)

Device Description:

Durepair® Dura Regeneration Matrix is a collagen implant for the repair of defects in the dura mater. Durepair® is supplied sterile in sheet form in a variety of sizes to be trimmed and; sutured or onlayed by the surgeon to meet the individual patient's needs.

Indications for Use:

Durepair® is indicated as a dura substitute for the repair of the dura mater.

K041660

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Statement of Substantial Equivalence:

Durepair® is substantially equivalent in function and intended use to:

Predicate Devices	Manufacturer	510(k) Number
Dura-Guard®	Bio-Vascular	K982282
DuraGen™	Integra Life Sciences	K982180

Summary of Technological Characteristics:

Safety of the Durepair® device to the predicate products was demonstrated in biocompatibility studies in accordance with ISO 10993, in vitro testing, animal studies, and clinical data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2004

Mr. Jeffrey Henderson
Vice President, Quality & Regulatory Affairs
Medtronic Neurosurgery
125 Cremona Drive
Goleta, California 93117-5500

Re: K041000
Trade/Device Name: Durepair® Dura Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: II
Product Code: GXQ
Dated: June 18, 2004
Received: June 21, 2004

Dear Mr. Henderson:

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" (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 (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

K041000

Indications for Use

510(k) Number (if known):

Device Name:

Durepair® Dura Regeneration Matrix

Indications for Use:

Durepair® is indicated as a dura substitute for the repair of the dura mater.

Miriam C. Provost

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

510(k) Number K041000

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)