

SEP 14 2005

7. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 307.87.

Address of Manufacturer:

TEI Biosciences Inc.
7 Elkins Street
Boston, MA 02127
(317) 268-1616
(317) 268-3282 (fax)
ERN 3004170064

Lyophilization Services of New England, Inc.
One Sundial Ave., Suite 112
Manchester, NH 03103
ERN 1225991

Contact Person:

Jeffrey Henderson
Vice President, Quality and Regulatory Affairs
Medtronic Neurosurgery
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 ext. 1773
Fax: (805) 968-9336
ERN 2021898

Date:

August 10, 2005

Trade or Proprietary Name:Durepair[®] Dura Regeneration MatrixCommon Usual or Classification Name:

Dura Substitute (882.5910)

Predicate Device Identification:Durepair[®] Dura Regeneration Matrix
(K041000)

Description: The 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 by the surgeon to meet the individual patient's needs.

Intended Use: Durepair is a dura substitute for the repair of the dura mater.

Intended Use of Predicate Device(s): The predicate device, Durepair, is a dura substitute for the repair of the dura mater.

Technological Comparison: Medtronic Neurosurgery submits that the collagen material, sourcing specification, fundamental scientific technological attributes, device labeling, and the intended use of the device are the same as the previously reviewed and cleared Durepair. Based upon the summary above, Medtronic Neurosurgery determines substantial equivalence, safety, and efficacy of the Durepair product compared to the predicate and currently marketed devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K052211
Trade/Device Name: Durepair[®] Dura Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura substitute
Regulatory Class: II
Product Code: GXQ
Dated: August 10, 2005
Received: August 16, 2005

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.

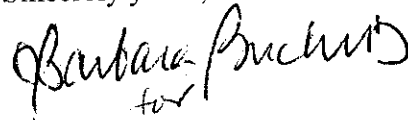
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Handwritten signature of Barbara Bruchman in cursive script.

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

Enclosure

II. Statement of Indications for Use

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.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchard for Myra

Division Sign-Off) Page 1 of 1

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K052211