K120600

JUN 15 2012

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) – Submitter Information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro NJ 08536
Phone Number	(609) 936-5526
Fax Number	(609) 275-9445
Establishment Registration Number	3003418325
Name of Contact Person	Aakash Jain
Date Prepared	May 4, 2012
807.92(a)(2) – Name of device	
Trade or Propriety Name	DuraGen® Secure Dural Regeneration Matrix
Common or Usual Name	Dura substitute
Classification Name	Dura Substitute
Classification Panel	Neurology
Regulation	Class II, under 21 CFR 882.5910
Product Code(s)	GXQ
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
DuraGen XS™ Dural Regeneration Matrix – K072207	
807.92(a)(4) - Device description	
DuraGen Secure Dural Regeneration Matrix is an absorbable implant for the repair of dura mater. This absorbable, sutureless onlay graft is comprised of a porous, highly purified collagen matrix and a thin layer of hydroxypropyl methyl cellulose (HPMC). HPMC is a non-cytotoxic, non-immunogenic, biocompatible plant-derived cellulose-based material. The addition of HPMC results in a dural graft which reduces the potential for the product to migrate, slide or displace during the surgical procedure, such as during irrigation of the surgical site or in a standing pool of fluid, without the use of sutures.	
807.92(a)(5) – Intended Use of the device	
Indications for Use	DuraGen® Secure Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater.
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
DuraGen Secure Dural Regeneration Matrix is similar to the predicate device, DuraGen XS Dural Regeneration Matrix (Integra LifeSciences) in terms of intended use, physical properties, and mechanical properties. DuraGen Secure is manufactured using a collagen matrix, which is made from the same raw materials as those used to manufacture DuraGen XS, and has an added thin layer of HPMC to one side of the collagen matrix which reduces the potential for the product to migrate, slide or displace during the surgical procedure, such as during irrigation of the surgical site or in a standing pool of fluid, without the use of sutures.	
Product	Comparision of DuraGen Secure to the predicate (DuraGen XS)

Characteristics	
Mechanical Properties (Suture Retention and Tensile Strength)	Similar
Thickness	Similar
Porosity	Similar
Transition Temperature	Similar
Wetting Time	Similar
Material(s)	• DuraGen Secure: Bovine Type I Collagen and Plant-Derived Hydroxypropyl Methylcellulose (HPMC) • DuraGen XS: Bovine Type I Collagen
Resistance to migration	• DuraGen Secure: Meets Slip and Submersion Tests Criteria • DuraGen XS: Does not meet Slip and Submersion Tests Criteria

807.92(b)(1-2) – Nonclinical Tests Submitted

In addition to mechanical testing, two animal studies were performed under GLP conditions comparing DuraGen Secure and the predicate device, DuraGen XS.

The first animal study was a canine duraplasty study in which the results presented similarly *in vivo*. Both articles produced minimal inflammation, vascularization, and foreign body response. The products were mostly resorbed by 90-days and completely resorbed by 180-days. They were both completely integrated by 90-days. Both followed a similar time course for tissue reaction. There was no evidence of CSF leak through clinical, gross, or microscopic observation. There was also no evidence of infection or hydrocephalus. Under the conditions of this study, DuraGen Secure was considered substantially equivalent to DuraGen XS.

A second canine efficacy study was performed in which the results demonstrated the increased resistance to migration of DuraGen Secure when compared to the predicate, DuraGen XS, during irrigation and exposure to the conditions of standing fluid in a surgical site.

Biocompatibility testing according to standards set forth in ISO 10993 demonstrated no systemic toxicity and that the device was non-irritating, non-sensitizing, non-mutagenic, non-cytotoxic, non-hemolytic, and non-pyrogenic. Pyrogenicity was evaluated using the Limulus Amebocyte Lysate (LAL) test on the final sterilized DuraGen Secure device and found to be less than 0.06 EU/ml (Endotoxin Units / ml) per *FDA 's Guidance Document for Dura Substitute Devices.* All DuraGen Secure lots will be tested prior to release to ensure they are less than 0.06 EU/ml and will be labeled non-pyrogenic.

807.92(b)(3) – Conclusions drawn from non-clinical data

Testing confirmed that DuraGen Secure meets the product specifications and is biocompatible. Testing has confirmed that the product is substantially equivalent to the predicate device, DuraGen XS. The modifications expressed in this 510(k) Premarket Notification do not change the intended use or fundamental scientific technology of the device, and does not raise any new issues of safety or effectiveness.

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

JUN 15 2012

Integra LifeSciences Corporation
c/o Mr. Aakash Jain
Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K120600
Trade/Device Name: DuraGen® Secure Dural Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: June 07, 2012
Received: June 08, 2012

Dear Mr. Jain:

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,

Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K120600

Indications for Use

510(k) Number (if known): K120600

Device Name:

DuraGen® Secure Dural Regeneration Matrix

Indications For Use:

DuraGen® Secure Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120600