DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 6, 2017

Integra LifeSciences Corporation
Yara Hamid
Regulatory and Quality Associate
311 Enterprise Dr.
Plainsboro, NJ 08536

Re: K163456
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: December 8, 2016
Received: December 9, 2016

Dear Ms. Yara Hamid:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163456

Device Name
DuraGen® Secure Dural Regeneration Matrix

Indications for Use *(Describe)*
DuraGen® Secure Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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2. 510(k) SUMMARY

DuraGen® Secure Dural Regeneration Matrix

Submitter's name and address:

Integra LifeSciences Corporation

311 Enterprise Drive

Plainsboro, NJ 08536 USA

Telephone: 609-275-0500

Cell: 609-275-5363

Contact person and telephone number:

Yara Hamid

Regulatory and Quality Associate

Date the Summary was prepared: November 11, 2016

Name of the device:

Proprietary Name: DuraGen® Secure Dural Regeneration Matrix

Common Name: Dura Substitute

Classification Name: Dura substitute

Product Code: GXQ

Regulation: Class II, under 21 CFR 882.5910

Substantial Equivalence:

DuraGen® Secure Dural Regeneration Matrix is substantially equivalent in function and intended use to the predicate device detailed in **Table 2-1**.

Table 2-1- Substantial Equivalence Table

510(k) Number	Product Code	Trade Name	Manufacturer
K120600	GXQ	DuraGen® Secure Dural Regeneration Matrix	Integra LifeSciences Corporation

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.

Indication for Use:

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

Summary of Technological Characteristics:

DuraGen® Secure Dural Regeneration Matrix has the same design, material, and chemical composition, as the predicate device (K120600). The manufacturing and processing are exactly the same and have no changed.

Testing and Test Results:

A viral inactivation study was conducted to demonstrate that DuraGen® Secure Dural Regeneration Matrix demonstrates continued conformance to *ISO 22442-3 Medical devices utilizing animal tissues and their derivatives -- Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*, FDA Recognition Number 15-47, through the combined enzymatic treatment and alkali treatment processes. These processes were performed in a validated scaled down process that is representative of all Integra LifeSciences Corporation's collagen products. The viral inactivation study resulted in a six log reduction of the viral titers. The results of the testing did not raise any new issues of safety or effectiveness compared to DuraGen® Secure Dural Regeneration Matrix.

Conclusion:

The DuraGen® Secure Dural Regeneration Matrix is substantially equivalent to the current marketed device, DuraGen® Secure Dural Regeneration Matrix. There have been no modifications to the design or manufacturing of the DuraGen® Secure Dural Regeneration Matrix that resulted in this filing, and the results of the viral inactivation study do not change the intended use or fundamental scientific technology of the device, and do not raise any new issues of safety or effectiveness.