DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2014

Integra LifeSciences Corporation
Ms. Nicole C. Harlan
Specialist, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K141841
Trade/Device Name: Integra MOZAIK™ Osteoconductive Scaffold – Strip (5cc)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 7, 2014
Received: July 8, 2014

Dear Ms. Harlan:

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" (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 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 yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K141841

Device Name: Integra MOZAIK™ Osteoconductive Scaffold – Strip (5cc)

Indications For Use: Integra MOZAIK™ Osteoconductive Scaffold – Strip is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. Integra MOZAIK™ Osteoconductive Scaffold – Strip is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), Integra MOZAIK™ Osteoconductive Scaffold – Strip is resorbed and replaced with bone during the healing process.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 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)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K141841

510(K) SUMMARY

Integra MOZAIK™ Osteoconductive Scaffold – Strip (5cc)

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Nicole C. Harlan
Specialist, Regulatory Affairs
Telephone: 609.750.2836
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Date Summary was prepared:

July 3, 2014

Name of the device:

Proprietary Name: Integra MOZAIK™ Osteoconductive Scaffold – Strip
Common Name: Bone void filler
Classification Name: Filler, Bone Void, Calcium Compound
Product Code: MQV

Substantial Equivalence:

The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip is indentical in formulation, function and intended use to the predicate device, 15cc Integra MOZAIK™ Osteoconductive Scaffold – Strip, detailed in the following table.

510(k) Number	Product Code	Trade Name	Manufacturer
K063124	MQV	Integra MOZAIK™ Osteoconductive Scaffold – Strip	Integra LifeSciences Corporation

Device Description:

The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip is a porous resorbable bone void filler made from highly purified bovine Type I collagen and calcium salt (β-Tricalcium phosphate Ca3(PO4)2 per ASTM F1088).

The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip bone grafting construct is designed to facilitate the repair of bony defects. The matrix has a three dimensional trabecular network of pores that resembles the pore structure of human cancellous bone. The three dimensional pore structure quickly imbibes fluids, making it easy to combine bone marrow aspirate.

The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip guides bone regeneration across a critical defect site into which the products are implanted. New bone forms in apposition to the matrix surface when the grafts are placed in direct contact with viable host bone. Ultimately, the matrices are resorbed and remodeled into bone.

The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip is provided sterile, non-pyrogenic, for single use in double peel packages.

Intended Use:
Integra MOZAIK™ Osteoconductive Scaffold – Strip is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Following placement in the bony void or gap (defect), 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip is resorbed and replaced with bone during the healing process.

Substantial Equivalence Comparison:
The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip has the same materials, design, performance, and indications for use as the commercially marketed devices, 10cc and 15cc Integra MOZAIK™ Osteoconductive Scaffold – Strip (K063124). The only difference between products will be in the mass and dimensions, the 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip being a smaller size offering.

Testing and Test Results:
The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip has the same materials, critical specifications and intended use as the 10cc and 15cc Integra MOZAIK™ Osteoconductive Scaffold – Strip.

Based on the recommendations of Guidance for Industry and FDA Staff – *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device (June 2, 2003)*, the 15cc Integra MOZAIK™ Osteoconductive Scaffold – Strip biocompatibility and *in vivo* performance testing will be applied to the 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip.

Performance tests were conducted to demonstrate equivalence between the 5cc and 15cc Integra MOZAIK™ Osteoconductive Scaffold – Strip and to ensure that 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip meets specification. All test results were acceptable.

Conclusion:
The 5cc Integra MOZAIK™ Osteoconductive Scaffold – Strip is substantially equivalent to the commercially marketed device, 15cc Integra MOZAIK™ Osteoconductive Scaffold – Strip (K063124).

The modifications expressed in this 510(k) Premarket Notification do not change the intended use or fundamental scientific technology of the device, and do not raise any new issues of safety or effectiveness.