February 21, 2025

RTI Surgical, Inc.
Ellen Rounds
Sr. Regulatory Affairs Specialist
11621 Research Circle
Alachua, Florida 32615

Re: K241555
Trade/Device Name: Moldable Bone Void Filler and Moldable Bone Void Filler + CCC
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: January 24, 2025
Received: January 24, 2025

Dear Ellen Rounds:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2025.02.21 11:57:51 -05'00'

Jesse Muir, PhD
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241555

Device Name
Moldable Bone Void Filler and Moldable Bone Void Filler + CCC

Indications for Use *(Describe)*
Moldable Bone Void Filler and Moldable Bone Void Filler + CCC is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Moldable Bone Void Filler and Moldable Bone Void Filler + CCC can be used with autogenous bone marrow. Moldable Bone Void Filler and Moldable Bone Void Filler + CCC resorbs and are replaced with bone during the healing process.

Moldable Bone Void Filler and Moldable Bone Void Filler + CCC are for single patient use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	02/20/2025
Submitter:	RTI Surgical, Inc. 11621 Research Circle Alachua, FL 32615 USA
Contact Information:	Ellen Rounds Sr. Regulatory Affairs Specialist Email: erounds@rtix.com
Name of Device:	Moldable Bone Void Filler and Moldable Bone Void Filler + CCC
Common Name:	Optecure and Optecure + CCC
Classification Name:	Resorbable calcium salt bone void filler device Filler, Bone Void, Calcium Compound
Regulation Number:	21 CFR 888.3045
Regulatory Class:	Class II
Product Code:	MQV, MBP
Panel:	Orthopedic
Legally Marketed Predicate Device(s):	Exactech Optecure and Optecure + CCC, K121989
Device Description:	Moldable Bone Void Filler and Moldable Bone Void Filler + CCC are bone void fillers composed of processed demineralized bone matrix (DBM), a synthetic macromer hydrogel, and cortical cancellous bone chips (CCC) for Moldable Bone Void Filler + CCC only. Both are provided with an accessory kit containing pre-measured hydrating solution and a spatula to mix the components. After the implant is hydrated, the resultant putty can then be handled and placed in the appropriate bone voids or gaps. Moldable Bone Void Filler and Moldable Bone Void Filler + CCC gradually resorb and are replaced with new bone during the healing process. At the 12 week timepoint, animal study data demonstrated new bone formation averages of 16.21% in the Optecure group, 13.8% in the Optecure + CCC group, 15.75% in the Exactech Optecure + CCC predicate group, and 12.08 % in the empty defect negative control group.
Indications for Use:	Moldable Bone Void Filler and Moldable Bone Void Filler + CCC is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Moldable Bone Void Filler and Moldable Bone Void Filler + CCC can be used with autogenous bone marrow. Moldable Bone Void Filler and Moldable Bone Void Filler + CCC resorbs and are replaced with bone during the healing process. Moldable Bone Void Filler and Moldable Bone Void Filler + CCC are for single patient use only.

Substantial Equivalence Comparison:	The subject device are demonstrated to be substantially equivalent to the predicate device cited above with respect to indications for use, materials, biocompatibility, storage, and performance.
Non-Clinical Performance Data:	In accordance with the "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device", the following testing has been performed to support substantial equivalence and to demonstrate safety and effectiveness • Chemical and physical properties • Biocompatibility • Sterility • Shelf Life • Animal Study At the 12 week timepoint, animal study data demonstrated new bone formation averages of 16.21% in the Optecure group, 13.8% in the Optecure + CCC group, 15.75% in the Exactech Optecure + CCC predicate group, and 12.08 % in the empty defect negative control group.
Clinical Performance:	There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.
Substantial Equivalence:	The determination of a device are substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the predicate devices. Additionally, if the device has the same intended use but different technological characteristics and can be demonstrated that the new device does not raise any safety and effectiveness concerns as compared to the predicate device. In the provided 510(k) submission the difference between the predicate device and Moldable Bone Void Filler and Moldable Bone Void Filler + CCC do not raise safety and/or effectiveness concerns. Therefore, Moldable Bone Void Filler and Moldable Bone Void Filler + CCC is determined to be substantially equivalent to the predicate device.
Conclusion:	The submitted 510(k) demonstrates Moldable Bone Void Filler and Moldable Bone Void Filler + CCC are substantially equivalent to the predicate device.