July 31, 2019

Inion Oy
Tiina Tyni
Regulatory Affairs Manager
Lääkärinkatu 2
Tampere 33520
Finland

Re: K191764
Trade/Device Name: Inion BioRestore
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 26, 2019
Received: July 1, 2019

Dear Tiina Tyni:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Laurence D. Coyne, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191764

Device Name
Inion BioRestore

Indications for Use *(Describe)*
These INION BIORESTORE™ implants are bone graft substitutes indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. INION BIORESTORE™ is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

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.

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K191764

SPECIAL 510(k) SUMMARY
Inion BioRestore - modification

4-1

Manufacturer and submitter	Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND
Date	June 26, 2019
Contact person	Tiina Tyni, Regulatory Affairs Manager Phone: +358 10 830 6600 Fax: +358 10 830 6601 tiina.tyni@inion.com
Establishment registration number	9710629
Trade name of the device	Inion BioRestore
Device classification and product code	Class II Classification Panel: Orthopaedic Product Code: MQV Common name: Filler, bone void, calcium compound Regulation number: 888.3045
Predicate device	Inion BioRestore (K070998)
Conformance with performance standards	Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

Inion BioRestore™ is a biodegradable bone graft substitute made of bioactive, biodegradable glass. Inion BioRestore™ system consists of different size cylinders, blocks and morsels made of degradable bioactive glass. When implanted, a kinetic modification of the surface occurs, resulting in the formation of a calcium phosphate layer that is essentially similar in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect. Based on pre-clinical testing, most of the material degrades in vivo in six months. The material is radiopaque. Inion BioRestore™ implants are intended for single use and are provided sterile to the user. They are completely synthetic and non-pyrogenic.

With this modification, additional packaging sizes and packaging configurations are introduced for the Inion BioRestore™ morsels.

SPECIAL 510(k) SUMMARY
Inion BioRestore - modification

Indications for use

These INION BIORESTORE™ implants are bone graft substitutes indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. INION BIORESTORE™ is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Similarities to predicate device

There are no changes to the implant, i.e. Inion BioRestore morsels are the same.

Differences to predicate device

New package sizes (5cc, 6cc, 8cc and 10cc) are added to the portfolio. These will be packaged in the new syringe packaging to improve handling properties.

New package sizes (0.25cc, 0.5 cc, 1 cc, 1.6 cc, 2.0 cc, 2.5 cc, 4.6 and 5.0 cc) are added to the portfolio. These will be packaged in the current packaging (tube).

Verification testing for substantial equivalence determination

Based on the risk analysis, the following verification/validation activities were identified and performed: biological safety evaluation was conducted for the new package configuration; sterilization validation was conducted; and shelf life studies were performed to confirm and verify the shelf life of five years for the new Inion BioRestore™ packaging configuration.

A transportation and handling test was performed to verify the ability of the packaging system to provide physical protection to the sterile barrier and to ensure that no damage of the products takes place, and that functionality of products is not compromised during shipping or handling. The results show that all acceptance criteria were fulfilled.

As demonstrated by the verification and validation testing, providing the new package sizes and package configurations of Inion BioRestore™ morsels do not raise new or increased risks concerning the safety or efficacy of the devices, when used in accordance with their indications for use. Inion BioRestore ™ morsels can be expected to perform safely and effectively in their intended use; and the product-specific benefits can be considered to clearly overweigh the identified product-specific risks.