January 13, 2021

Inion Oy
Kati Marttinen
VGM Quality and Regulatory
Laakarinkatu 2
Tampere, 33520
Finland

Re: K203105
Trade/Device Name: Inion CompressOn Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 9, 2020
Received: October 15, 2020

Dear Kati Marttinen:

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,

For; Shumaya Ali, MPH
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)*
K203105

Device Name
Inion CompressOn™ Screw

Indications for Use *(Describe)*
The Inion CompressOn™ products are intended for maintenance of alignment and fixation of bone fractures, comminuted fractures, osteotomies, arthrodeses or bone grafts (i.e., autografts or allografts) in the presence of appropriate additional immobilization (e.g., rigid fixation implants, cast or brace).

In addition, the Inion CompressOn™ Ø 3.5/4.0/4.5/5.0/6.0 mm products are specifically intended for use in following indications:
A. General indication: maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.
B. Specific indications: fractures and osteotomies of the malleoli, and ankle fractures.

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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"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

Inion CompressOn™ Screw

Manufacturer and submitter:	Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND
Date:	December 11, 2020
Contact person	Kati Marttinen, VGM Quality and Regulatory Phone: +358 10 830 6600 Fax: +358 10 830 6691 kati.marttinen@inion.com
Establishment registration number	9710629
Trade name of the device	Inion CompressOn™ Screw
Device classification and product code	Class II Classification Panel: Orthopaedic Product Code: HWC Common name: Bone fixation screw Regulation number: 888.3040
Predicate device	Inion FreedomScrew™ (K123672)
Conformance with performance standards	Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

Inion CompressOn™ Screws are cannulated headless compression screws made of degradable co-polymers composed of L-lactic acid and D-lactic acid. These polymers have a long history of safe medical use and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolised by the body. The implants retain sufficient strength to fulfil their intended function during the healing period of the fracture or osteotomy, and degrade gradually thereafter. Bioresorption takes place within two to four years. The implants are provided sterile to the user and are not to be re-used or re-sterilized.

Inion CompressOn™ Screws have nominal dimensions ranging from 2.7–6.0 mm in diameter and 12-90 mm in length. They are designed to be inserted using Inion® instrumentation: drill bits, bone taps, drill taps, screwdriver shafts, drill sleeves, K-wires and depth gauges. The screws can be inserted over a guide wire.

Inion CompressOn™ Screws provide fixation and are not intended to replace healthy bone or withstand the stress of full load bearing.

510(k) SUMMARY
Inion CompressOn™ Screw

Indications for use

The Inion CompressOn™ products are intended for maintenance of alignment and fixation of bone fractures, comminuted fractures, osteotomies, arthrodeses or bone grafts (i.e., autografts or allografts) in the presence of appropriate additional immobilization (e.g., rigid fixation implants, cast or brace).

In addition, the Inion CompressOn™ Ø 3.5/4.0/4.5/5.0/6.0 mm products are specifically intended for use in following indications:
A. General indication: maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.
B. Specific indications: fractures and osteotomies of the malleoli, and ankle fractures.

Comparison with predicate device

The Inion CompressOn™ Screws have the same material composition, manufacturing method and indications for use as the predicate device. The differences compared to the predicate device are:

- Inion CompressOn™ Screws include larger diameter designs (5.0/6.0 mm)
- Inion CompressOn™ Screws are headless to reduce the risk of palpability/irritation
- Inion CompressOn™ Screws provide compression to the fracture/osteotomy line
- Inion CompressOn™ Screws do not include a disposable insertion adapter
- Inion CompressOn™ Screws are not intended for plate fixation.

Performance testing for substantial equivalence determination

Mechanical torsion testing was conducted to determine and verify the sufficient mechanical properties of the Inion CompressOn™ screws for insertion. A mechanical pull-out test was conducted to verify that the pull-out properties of Inion CompressOn™ Screw are substantially equivalent with the predicate device Inion FreedomScrew™. The mechanical tests were conducted according to FDA recognized consensus standard *ASTM F2502-11 Standard specification and test methods for absorbable plates and screws for internal fixation implants.* In vitro degradation test was conducted in accordance with FDA recognized consensus standards *ISO 13781:2017 Implants for surgery - Homopolymers, copolymers and blends on poly(lactide) - In vitro degradation testing* and *ASTM F1635-16 Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants*, to verify that the degradation rate and pull-out properties of Inion CompressOn™ Screw are substantially equivalent with the predicate device Inion FreedomScrew™ initially and over the healing period. The choice of test material was done in accordance with FDA recognized consensus standard *ASTM F1839-08 (Re-approved 2016) Standard specification for rigid polyurethane foam for use as a standard material for testing orthopaedic devices and instruments.*

Functional and handling test and simulated clinical use test were performed to verify that the implants, accessory instruments, packaging and instructions for use are functioning together as intended, and conform to the defined user needs and intended uses.

510(k) SUMMARY
Inion CompressOn™ Screw

Conclusions

The data demonstrates that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion CompressOn™ Screws are substantially equivalent with the predicate device Inion FreedomScrew™ (K123672). The devices have passed the tests for functionality and handling in simulated clinical use settings.