Inion Oy
Hanne Kankaanpää
Senior Regulatory Affairs Manager
Lääkärinkatu 2
Tampere, FI-33520
FINLAND

November 7, 2025

Re: K251441
Trade/Device Name: Inion CPS 1.5 Baby Bioabsorbable Fixation System; Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: October 10, 2025
Received: October 10, 2025

Dear Hanne Kankaanpää:

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K251441

Device Name
Inion CPS 1.5 Baby Bioabsorbable Fixation System
Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System

Indications for Use *(Describe)*

The INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM implants are intended for use in trauma and reconstructive procedures in the mid-face and maxilla of infant (from 29 days to 2 years of age) and child (greater than 2 years to 12 years of age) patients.

Specific indications:
- congenital anomalies correction in the orbital rim, orbital floor, maxilla and midface
- traumatic injuries.

The INION CPS™ 1.5/2.0/2.5 BIOABSORBABLE FIXATION SYSTEM implants are intended for use in trauma and reconstructive procedures, and to maintain the relative position of bone grafts or bone graft substitutes, in orbital floor, medial and lateral orbital walls, orbital rim, mid-face, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation) of child (greater than 2 years to 12 years of age), adolescent (greater than 12 years through 21 years of age) and adult patients. Specific indications: fixation of LeFort (I, II, III) osteotomies and mandibular orthognathic procedures

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
Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System
Inion CPS™ Baby 1.5 Bioabsorbable Fixation System

A. Device information:

Sponsor:	Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND
Correspondent contact information:	Hanne Kankaanpää Lääkärinkatu 2, FIN-33520 Tampere, FINLAND hanne.kankaanpaa@inion.com +358 10 830 6600
Date of Summary:	November 7th, 2025
Establishment registration number:	9710629
Device common name:	Bone plate
Device Regulation and name:	872.4760 Bone Plate, 872.4880 Screw, fixation, intraosseous
Classification and product code: **510(k) number:**	Class II JEY, DZL K251441
Device Proprietary name:	Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System Inion CPS™ 1.5 Baby Bioabsorbable Fixation System

Predicate Device Information:

Predicate Device:	Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System
Predicate Device Manufacturer:	Inion Oy
Predicate Device Common Name:	Bone Plate
Predicate Device Premarket Notification #	K010352, K122890, K013039, K022981, K020266
Predicate Device Classification & Name	872.4760 Plate, Bone 872.4880 Screw, fixation, intraosseous
Predicate Device Classification & Product Code:	Class II 510(k) JEY, DZL

Predicate Device:	Inion CPS™ Baby 1.5 Bioabsorbable Fixation System
Predicate Device Manufacturer:	Inion Oy
Predicate Device Common Name:	Bone Plate
Predicate Device Premarket Notification #	K010351, K033194
Predicate Device Classification & Name	872.4760 Plate, Bone
Predicate Device Classification & Product Code:	Class II 510(k) JEY

B. Device description and principles of operation

Inion CPS™ and Inion CPS™ Baby implants are bioabsorbable plates, screws and mesh plates made of bioabsorbable co-polymers. Inion CPS™ 1.5/2.0/2.5 System implants are composed of L-lactic acid, D-lactic acid and Trimethylenecarbonate. Inion CPS™ 1.5 Baby System implants are composed of L-lactic acid, D-lactic acid and Poly-Glygolic 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 of Inion CPS™ implants takes place within 2-4 years, and Inion CPS™ Baby implants within 2-3 years.

The systems consist of fixation plates, meshes and screws offered in different sizes and designed to be used with the Inion CPS™ bone drill bits, bone taps, self-drilling bone taps, countersinks, screw drivers, plate bending pliers and heating device. Nonsterile instruments are intended to be cleaned and sterilized before initial use and after each use.

The implants are provided sterile by gamma irradiation. They are intended for single use and shall not be re-sterilized or re-used. Implants are non-pyrogenic and fully synthetic. The Subject Device is not intended for use in the orbital roof and can only be used if no exposure of the intracranial compartment is presented.

C. Intended use / Indications for use

The INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM implants are intended for use in trauma and reconstructive procedures in the mid-face and maxilla of infant (from 29 days to 2 years of age) and child (greater than 2 years to 12 years of age) patients.

Specific indications:
- congenital anomalies correction in the orbital rim, orbital floor, maxilla and midface
- traumatic injuries.

The INION CPS™ 1.5/2.0/2.5 BIOABSORBABLE FIXATION SYSTEM implants are intended for use in trauma and reconstructive procedures, and to maintain the relative position of bone grafts or bone graft substitutes, in orbital floor, medial and lateral orbital walls, orbital rim, mid-face, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation) of child (greater than 2 years to 12 years of age), adolescent (greater than 12 years through 21 years of age) and adult patients. Specific indications:
- fixation of LeFort (I, II, III) osteotomies and mandibular orthognathic procedures.

D. Comparison of the Technological characteristics

Characteristic	Application Device: Inion CPS Baby 1.5 Bioabsorbable Fixation System K251441	Predicate Device: Inion CPS Baby 1.5 Bioabsorbable Fixation System K010351, K033194	Impact on Substantial Equivalence
Company	Inion Oy	Inion Oy	-
Regulation Number	872.4760	872.4760	Identical
Product Code	JEY	JEY	Identical
Intended Use	INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM implants are bioabsorbable internal fixation devices intended for fixation of bone tissue in trauma and reconstructive procedures.	INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM implants are bioabsorbable internal fixation devices intended for fixation of bone tissue in trauma and reconstructive procedures.	Identical
Indications for Use	INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM implants are intended for use in trauma and reconstructive procedures in the mid-face and maxilla of infant (from 29 days to 2 years of age) and child (greater than 2 years to 12 years of age) patients. Specific indications: - congenital anomalies correction in the orbital rim, orbital floor, maxilla and midface - traumatic injuries.	A. General indications: The INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, mid-face and maxilla. B. Specific indications: • Fractures of the cranium, mid-face and maxilla • Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations) • LeFort (I, II, III) osteotomies • Pediatric reconstructive procedures • Orthognathic or reconstructive procedures of the cranium, mid-face, or maxilla • Craniotomy flap fixation	Similar – the wording is narrowed down for devices intended for the midface and maxilla region. The new wording includes target patient populations.

Characteristic	Application Device: Inion CPS Baby 1.5 Bioabsorbable Fixation System K251441	Predicate Device: Inion CPS Baby 1.5 Bioabsorbable Fixation System K010351, K033194	Impact on Substantial Equivalence
Technology	Bioabsorbable copolymer implants	Bioabsorbable copolymer implants	Identical
Design	Inion CPS Baby 1.5 mm 20 hole plate Inion CPS Baby 1.5 Mesh plate (K010351) 7 x 7 holes L/W 45 x 45 mm Inion CPS Baby 1.5 Mesh plate (K010351) 14 x 14 holes L/W 90 x 90 mm	Inion CPS Baby 1.5 mm 20 hole plate (K010351) Inion CPS Baby 1.5 Mesh plate (K010351) 10 x 10 holes L/W 53 x 53 mm Inion CPS 1.5 Mesh plate (K010351) 20 x 20 holes LW 107 x 107 mm	One hole in the center removed (made as a solid part). Thickness tolerance adjusted. Since the predicate device clearance these minor changes have been made for the mesh designs. No change in implant thickness. The devices have been on the market with these slightly amended designs, since starting their commercial distribution.
Features	Material composition: L-lactic acid, glycolic acid and trimethylene carbonate Implants retain minimum of 70 % of their initial strength 6 weeks after implantation. Bioresorption takes place within two to three years.	Material composition: L-lactic acid, glycolic acid and trimethylene carbonate Implants retain minimum of 70 % of their initial strength 6 weeks after implantation. Bioresorption takes place within two to three years.	Identical – no changes to device materials or manufacturing methods.

Characteristic	Application Device: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System K251441	Predicate Device: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System K010352, K122890, K013039, K022981, K020266	Impact on Substantial Equivalence
Company	Inion Oy	Inion Oy	-
Regulation Number	872.4760 Bone Plate 872.4880 Screw, fixation, intraosseous	872.4760 Bone Plate 872.4880 Screw, fixation, intraosseous	Identical
Product Code	JEY, DZL	JEY, DZL	Identical
Intended Use	INION CPS™ 1.5/2.0/2.5 BIOABSORBABLE FIXATION SYSTEM implants are bioabsorbable internal fixation devices intended for fixation of bone tissue in trauma and reconstructive procedures.	INION CPS™ 1.5/2.0/2.5 BIOABSORBABLE FIXATION SYSTEM implants are bioabsorbable internal fixation devices intended for fixation of bone tissue in trauma and reconstructive procedures.	Identical
Indications for Use	INION CPS™ 1.5/2.0/2.5 BIOABSORBABLE FIXATION SYSTEM implants are intended for use in trauma and reconstructive procedures, and to maintain the relative position of bone grafts or bone graft substitutes, in orbital floor, medial and lateral orbital walls, orbital rim, mid-face, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation) of child (greater than 2 years to 12 years of age), adolescent (greater than 12 years through 21 years of age) and adult patients. Specific indications: fixation of LeFort (I, II, III) osteotomies and mandibular orthognathic procedures.	A. General indications: The INION CPS™ 1.5/2.0/2.5 BIOABSORBABLE FIXATION SYSTEM is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, mid-face, maxilla and mandible (in conjunction with appropriate maxillomandibular fixation). The INION CPS® Orbital Plates are intended for use in trauma and reconstructive procedures of the orbital cavity as part of the INION CPS™ 1.5/2.0/2.5 BIOABSORBABLE FIXATION SYSTEM. B. Specific indications: • Fractures of the cranium, mid-face, maxilla and mandible • Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations) • LeFort (I, II, III) osteotomies • Pediatric reconstructive procedures • Orthognathic or reconstructive procedures of	Similar — the wording is shortened, and narrowed down for devices for the midface, maxilla and mandible region. The new wording includes target patient populations.

Characteristic	Application Device: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System K251441	Predicate Device: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System K010352, K122890, K013039, K022981, K020266	Impact on Substantial Equivalence
		the cranium, mid-face, maxilla or mandible • Craniotomy flap fixation C. Additional indications: The INION CPS™ 2.0/2.5 BIOABSORBABLE FIXATION SYSTEM meshes and screws (ref numbers PLT-1032, PLT- 1033, PLT-1034, PLT-1035, SCR-1224, SCR-1225, SCR-1206, SCR-1207, SCR-1208, SCR-1290, SCR-1291, SCR-1292, SCR-1293, SCR- 1294, SCR-1297, SCR-1298, SCR-1299, SCR-1300, SCR-1301, SCR-1209) are intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive procedures involving: • Iliac crest harvest sites.	
Technology	Bioabsorbable copolymer implants	Bioabsorbable copolymer implants	Identical
Design	Inion CPS 1.5 system 20-hole plate Inion CPS 1.5 Mesh plate, 7 x 7 holes, L/W 45 x 45 mm Inion CPS 1.5 Mesh plate, 14 x 14 holes, L/W 90 x 90 mm Inion CPS 2.0 Mesh plate, 7 x 7 holes, L/W 45 x 45 mm Inion CPS 2.0 Mesh plate	Inion CPS 1.5 system (K010352) 20-hole plate Inion CPS 1.5 Mesh plate (K010352) 10 x 10 holes. L/W 53 x 53 mm Inion CPS 1.5 Mesh plate (K010352) 20 x 20 holes, L/W 107x107mm Inion CPS 2.0 Mesh plate (K010352) 8 x 8 holes, L/W 46 x 46 mm Inion CPS 2.0 Mesh plate (K010352)	One hole in the center removed (made as a solid part). Thickness tolerance adjusted. Since the predicate device clearance these minor changes have been made for the mesh designs. No change in implant thickness. The devices have been on the market with these slightly amended designs, since starting their commercial distribution.

Characteristic	Application Device: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System K251441	Predicate Device: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System K010352, K122890, K013039, K022981, K020266	Impact on Substantial Equivalence
	14 x 14 holes, L/W 90 x 90 mm Inion CPS 2.5 Mesh plate, 7 x 7 holes, L/W 45 x 45 mm Inion CPS 2.5 Mesh plate, 14 x 14 holes, L/W 90 x 90 mm Inion CPS 2.5 system 4 hole plate, extended long L/W/T 36.5 x 8.5 x 1.7 mm Inion CPS Ø2.0 screws L: 9, 11, 13, 15, 17, 20 mm Inion CPS Ø2.5 screws L: 10, 12, 14, 16, 18 mm	16 x 16 holes, L/W 93 x 93 mm Inion CPS 2.5 Mesh plate (K010352) 8 x 8 holes, L/W 49 x 49 mm Inion CPS 2.5 Mesh plate (K010352) 16 x 16 holes, L/W 99 x 99 mm Inion CPS 2.5 system (K010352) 4 hole plate, long L/W/T 32.5 x 8.5 x 1.7 mm Inion CPS Ø2.0 screws (K010352) L: 5, 7 mm Inion CPS Ø2.5 screws (K010352) L: 6, 8, 23 mm	Since the predicate device clearance, a slightly longer plate was added to the portfolio. Since the predicate device clearance, additional screw sizes were added to the portfolio.
Features	Material composition: L-lactic acid, D-lactic acid and trimethylene carbonate Implants retain minimum of 70 % of their initial strength 9 weeks after implantation. Bioresorption takes place within two to four years.	Material composition: L-lactic acid, D-lactic acid and trimethylene carbonate Implants retain minimum of 70 % of their initial strength 9 weeks after implantation. Bioresorption takes place within two to four years.	Identical – no changes to device materials or manufacturing methods.

E. Summary of Supporting data

Biocompatibility / non-pyrogenicity

There have been no changes to the materials or manufacturing methods of the Inion CPS™ and CPS™ Baby implants, which have been evaluated in accordance with *ISO 10993-1:2018* and FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing" within a risk management process, September 2023,* submitted with the most recent clearance of the Inion CPS™ and CPS™ Baby implants (K251472), covering also the subject devices.

Endotoxin specification limit for Inion implants is based on FDA recommendation which is based on *USP 2011 Chapter <161>*. The results of long-term periodical endotoxin testing show constantly low endotoxin level of the devices, the results being clearly below the acceptance limit.

Rabbit pyrogen test is currently recommended for detection of material-mediated pyrogenicity according to *"FDA Guidance 2012: Pyrogen and endotoxins testing questions and answers", "FDA Guidance 2016: Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile"*, and standard *ISO 10993-11:2017, Annex G*. Rabbit pyrogen tests were conducted for Inion CPS™ and CPS™ Baby implants. Representative samples of the subject devices were selected representing all different material constituents. The test articles were evaluated for their potential to induce a pyrogenic response following intravenous injection in rabbits based on the *United States Pharmacopeia (General chapter <151 >)*. Under the conditions of the study, the test articles met the requirements of the United States Pharmacopeia. The test articles were judged non-pyrogenic.

Clinical evaluation / target patient groups

Clinical evaluation was conducted on the published clinical studies of Inion CPS™ Baby 1.5 Bioabsorbable Fixation System and Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System, to support the determination of the target patient populations based on clinical data in accordance with *FDA Guidance - "Premarket Assessment of Pediatric Medical Devices"(March 2014), FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" (August 2017) and "Acceptance of Clinical Data to Support Medical Device Applications and Submissions Frequently Asked Questions" (February 2018).*

Performance testing

Mechanical testing was conducted to determine and verify the torsional properties of the longest Inion CPS™ Ø2.0 mm screw, to ensure adequate strength for its intended use and that the screw material does not yield under clinically relevant conditions. Testing was performed based on the applicable guidelines in the FDA recognized consensus standards *ASTM F543-23 Standard Specification and Test Methods for Metallic Medical Bone Screws* and *ASTM F2502-24*

Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants (rev -17 approved).

Most recent, completed shelf life test reports of Inion CPS™ Baby 1.5 Bioabsorbable Fixation System and Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System up to 3 years have been reviewed under the recent clearance of the Inion CPS™ and CPS™ Baby implants (K251472), covering also the subject devices. Shelf life of Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System has been extended to 5 years. The test included analysis of material properties, shear test during in vitro degradation for screws, bending test during in vitro degradation for plates and integrity of the sterile package system. Testing was performed based on the FDA recognized consensus standards as applicable: *ISO 13781:2017 Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing; ASTM F1635-24 Standard test method for in vitro degradation testing of hydrolytically degradable polymer resins and fabricated forms for surgical implants (rev -16 approved); ASTM D790-17 Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials; ASTM F2338-24 Standard test method for nondestructive detection of leaks in packages by vacuum decay method (rev -20 approved); ASTM F88/F88M-23 Standard test method for seal strength of flexible barrier materials; ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.*

Sterilization validation of the subject devices has been reviewed under K251472, covering also the subject devices. The applied FDA recognized consensus standards are *ANSI/AAMI/ISO 11137-1:2015/A2:2019 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*; *ISO 11137-2:2019 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose (rev 2013/Amd. 2022 approved) ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products; ISO 11737-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process, and ISO 11737-3:2023 Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing.*

F. Discussion of Performance testing

Material mediated pyrogenicity tests were conducted based on the United States Pharmacopoeia (General Chapter <151>) for the potential of the implants to induce a pyrogenic response following intravenous injection in rabbits, to support the claim of non-pyrogenicity. The results show that the devices are non-pyrogenic.

Supporting clinical data for mid-face, maxilla and mandible indications consists of 38 publications including 1738 patients with Inion CPS™ 1.5/2.0/2.5 system. While there is a limited number of clinical studies on the use of Inion CPS™ Baby 1.5 System in the areas of midface and maxilla, the material safety, suitable degradation profile and successful bone healing of the Inion CPS Baby 1.5 implants have been demonstrated with extensive number of

studies in pediatric cranial reconstructive procedures (some of which included the specific midface and maxilla defects), including over 200 pediatric patients and up to 10 years of follow-up. Based on the evidence provided in the supporting clinical data, including midface and maxilla in the indications for pediatric patients is not expected to raise new risks. Reference is made to 510(k) cleared devices with same or similar material composition indicated for the maxillofacial surgeries of pediatric patients (K062789, K992158).

The results of the mechanical torsion test show that the products meet the predefined safety acceptance criteria, and provide the necessary safety margin to account for clinical variability, including additional safety against unexpected over-torquing. The torsional properties of the longest Inion CPS™ Screw of Ø2.0 mm are substantially equivalent with the predicate device Inion CPS™ Ø2.0 mm screws (K010352).

Shelf life test has been completed for the Inion CPS™ 1.5 Baby Bioabsorbable Fixation System devices up to 3 years and for the Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System devices up to 5 years. The results show that the mechanical and material properties of the implants are not affected during ageing and the package system maintains the sterility through the shelf life.

G. Conclusion

Clinical evidence demonstrates the safety and effectiveness of the Inion CPS™ and Inion CPS™ Baby implants when used to treat the defined target populations. Testing in accordance with USP <151> and LAL Endotoxin testing shows that the devices are non-pyrogenic and can be labelled as such. Testing of mechanical and material properties of the implants initially and through the labelled shelf life demonstrates that the implants are substantially equivalent with predicate devices and do not raise new questions of safety or efficacy.