July 11, 2025

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

Re: K251472
Trade/Device Name: Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System; Inion CPS 1.5 Baby Bioabsorbable Fixation System
Regulation Number: 21 CFR 882.5360
Regulation Name: Cranioplasty Plate Fastener
Regulatory Class: Class II
Product Code: HBW
Dated: May 13, 2025
Received: May 13, 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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.07.11 09:45:47 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251472

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)*

Inion CPS™ 1.5 Baby Bioabsorbable Fixation System implants are intended for use in trauma and reconstructive procedures in the craniofacial skeleton (e.g., infant craniofacial surgery, craniosynostosis, congenital malformations, craniotomy flap fixation), mid-face and maxilla.

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 the cranium, including craniotomy flap fixation.

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.

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Inion Oy

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

A. Device Information:

510(k) Summary

Category	Information
Sponsor:	Inion Oy Laakarinkatu 2 Tampere Fl-33520 Finland Tel # 358108306600
Correspondent Contact Information:	Mrs. Hanne Kankaanpaa Laakarinkatu 2 Tampere Fl-33520 Finland hanne.kankaanpaa@inion.com
Device Common Name:	Bone Plate
Device Regulation & Name:	882.5360 Cranioplasty Plate Fastener
Classification & Product Code: 510(k) Number:	HBW K251472
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
Predicate Device Classification & Name	872.4760 Plate, Bone
Predicate Device Classification & Product Code:	Class II 510(k) JEY

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 #	K01035, K033194, K051341, K052444
Predicate Device Classification & Name	872.4760 Plate, Bone
Predicate Device Classification & Product Code:	Class II 510(k) JEY

B. Date Summary Prepared

July 8th, 2025

C. Description of Device

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. The instruments are nonsterile and reusable. They 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.

D. Indications for Use

The INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM implants are intended for use in trauma and reconstructive procedures in the craniofacial skeleton (e.g., infant craniofacial surgery, craniosynostosis, congenital malformations, craniotomy flap fixation).

The INION CPS™ l .5/2.0 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 the cranium, including craniotomy flap fixation.

E. Comparison of the Technological Characteristics

Characteristic	Application Device: Inion CPS Baby 1.5 Bioabsorbable Fixation System K251472	Predicate Device: Inion CPS Baby 1.5 Bioabsorbable Fixation System K010351, K033194, K051341, K052444	Impact on Substantial Equivalence
Company	Inion Oy	Inion Oy	-
Regulation Number	872.4760	872.4760	Identical
Product Code	JEY, HWC	JEY	Identical
Intended Use **Indications for 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 intended for use in trauma and reconstructive procedures in the craniofacial skeleton (e.g., infant craniofacial surgery, craniosynostosis, congenital malformations, craniotomy flap fixation)	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. 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	Identical Similar – wording shortened and narrowed down for neurology devices.
Technology	Bioabsorbable copolymer implants	Bioabsorbable copolymer implants	Technology is identical.

Characteristic	Application Device: Inion CPS™ Baby 1.5 Bioabsorbable Fixation System K251472	Predicate Device: Inion CPS™ Baby 1.5 Bioabsorbable Fixation System K010351, K033194, K051341, K052444	Impact on Substantial Equivalence
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 K251472	Predicate Device: Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System K010352	Impact on Substantial Equivalence
Company	Inion Oy	Inion Oy	-
Regulation Number	872.4760	872.4760	Identical
Product Code	JEY, HWC	JEY	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	The INION CPS™ 1.5/2.0 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 the cranium, including craniotomy flap fixation.	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™	Similar – wording shortened and narrowed down for neurology devices.

		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 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	Technology is identical.
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.

F. 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.*

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 to define suitable pediatric target patient groups for the devices. Supporting clinical data consists of 11 publications including 240 patients treated with Inion CPS™ Baby, and of 39 publications including 1755 patients with Inion CPS™ 1.5/2.0/2.5 system. The clinical data in terms of device performance and occurrence rate of adverse events has been fully evaluated in the Clinical Evaluation Report of the subject devices which is regularly updated. In the published clinical studies of Inion CPS™ and CPS™ Baby used in the treatment of the target patient populations, the performance rate and overall complication rate are well within the range of state-of-the-art devices and have remained steady throughout the years.

G. 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.

Clinical evaluation was conducted on published literature of the Inion CPS™ and Inion CPS™ Baby devices to support the determination of the target patient populations based on clinical data. Clinical evidence and post market follow-up data demonstrate the safe and effective use of Inion CPS™ Baby 1.5 Bioabsorbable Fixation System in infant and child patients in cranial procedures. Bioabsorbable products provide several benefits to the patients in comparison to the metal implants such as avoiding growth restriction of the developing skull and avoidance of removal procedures. The overall residual risk can be considered to be acceptable, and the benefit-risk ratio is clearly positive. The intended target patient groups for the Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System in the cranial indications are adult patients and there is no change to the predicate device in this regard.

H. Conclusion

Clinical evidence and post market follow-up data demonstrate the Inion CPS™ Baby 1.5 Bioabsorbable Fixation System as safe and effective as the predicate. The intended target patient groups for the Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System in the cranial indications are adult patients and there is no change to the predicate device in this regard.