



510(k) SUMMARY

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Inion® CPS/OTPS FreedomPlate™

JAN 23 2007

Indications for use

A. General indications: In the presence of appropriate additional immobilization or fixation, indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures, and cement restriction in total joint arthroplasty procedures.

B. Specific indications:

1. Craniofacial skeleton, cranium, mid-face, maxilla, and mandible
2. Metacarpus, proximal and middle phalangeal bones
3. Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax

Substantial equivalence to marketed products

Based on the performance data and specifications presented, it can be concluded that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion CPS/OTPS FreedomPlate™ are substantially equivalent with the predicate devices Inion® CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352), Inion® OTPS™ Biodegradable Mini Plating System (K023887) and Inion® OTPS™ Biodegradable Mesh Plating System (K031961).

Inion CPS/OTPS FreedomPlate™ is substantially equivalent to predicate Class II devices, when used, in the presence of appropriate additional immobilization or fixation, for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures, and cement restriction in total joint arthroplasty procedures, because the differences between Inion CPS/OTPS FreedomPlate™ and the predicate devices do not raise new questions of safety and effectiveness.

510(k) SUMMARY

Inion® CPS/OTPS FreedomPlate™

Manufacturer and submitter

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Establishment registration number

9710629

Trade name of the device

Inion® CPS/OTPS FreedomPlate™

Device classification and product code

Class II

Classification Panel: Orthopedic

Product Code: HRS

Common name: Plate, fixation, bone

Regulation number: 21 CFR 888.3030

Predicate devices

Inion® CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352)

Inion® OTPS™ Biodegradable Mini Plating System (K023887)

Inion® OTPS™ Biodegradable Mesh Plating System (K031961)

Conformance with performance standards

No applicable mandatory performance standards exist for this device.

Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

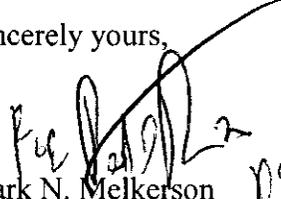
Inion CPS/OTPS FreedomPlate™ implants are made of resorbable polylactic acid / trimethylenecarbonate copolymers and they are provided in sizes typical to this application. Inion CPS/OTPS FreedomPlate™ implants gradually lose their strength during 18-36 weeks in vivo. Bioresorption takes place within two to four years.

Inion CPS/OTPS FreedomPlate™ implants are provided sterile to the user. The shelf life of the device is 3 years.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DGP 1/22/07
D.M. [unclear]

Enclosure

Statement of Indications for Use

510(k) Number: K063410

Device Name: Inion® CPS/OTPS FreedomPlate™

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)


(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)
**Division of General, Restorative,
and Neurological Devices**

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