K100205

Section 5
510k Summary

DEC 13 2010

The following information is provided as required by 21 CFR 807.87 for the 510(k) premarket notification for the plate and screw system, Frontier Devices Neuro Closure System. It has been revised from the original 510k Summary submitted in January 2010 in accordance with FDA requests.

Date Prepared:	November 30, 2010
Sponsor :	Frontier Devices 153A Cahaba Valley Parkway Pelham, AL 35124
FDA Registration #:	1065595
Contact Person:	Don Petersen, Ph.D. Director Quality Assurance and Regulatory Affairs 205-733-0901 (phone) 205-733-8445 (fax) dpetersen@frontierdevices.com
Proprietary Names:	Frontier Devices Neuro Closure System
Common Names:	Bone plates and screws
Regulation Number:	882.5320
Classification Name:	Preformed alterable cranioplasty plate
Product Codes:	GWO Plate, cranioplasty, preformed, alterable HBW Fastener, Plate, Cranioplasty GXR Cover, Burr hole
Device Classification:	Class II
Panel:	Intraocular, Corneal, and Neuromaterials Devices Branch
Predicate Devices:	Synthes Low Profile Neuro System (K042987) Synthes 2.0 mm Titanium T-Plate (K072758) Synthes Cranial Spring (K974206)

Device Descriptions:

Frontier Devices Neuro System

The Frontier Devices Neuro System consists of titanium bone plates and screws of various shapes and sizes.

Plates

The plates are made from unalloyed titanium that conforms to the ASTM F67 standard. Plates are 0.4 and 0.6 mm thick and come in a variety of shapes and sizes that are designed for cranial closure applications. The shapes and corresponding sizes include:

Straight plates	9-12mm long (1x1, 2x2, 5 and 7 holes)
Box plates	10mm x 10mm to 16mm x 16mm (4 hole)
X-plate	8mm x 8mm (4 hole)
Y-plate	16mm long (6 and 8 holes)

Double Y-plate	18mm to 21mm long (6 and 8 hole)
Strut plate	24 and 35mm long (6 and 8 hole)

Burr Hole Covers

The burr hole covers are are made from unalloyed titanium that conforms to the ASTM F67 standard. They are 0.4 and 0.6 mm thick and are circular in shape with equi-spaced drill holes around the circumference. The burr hole covers have two basic shapes. The burr hole cover for shunt has a segment of the circular burr hole cover missing which is where a shunt device is placed. The other burr hole cover is a complete circle. The corresponding sizes include:

Burr hole covers	12mm to 24mm diameter
Burr hole covers for shunt	12mm to 24mm diameter

Mesh

The mesh is made from unalloyed titanium that conforms to ASTM F67 standard. They are 0.4 and 0.6mm thick and rectangular in shape, 90mm x 120mm.

Screws

The screws are self-drilling screws that do not require a pre-drilled pilot hole and are made from a titanium alloy, Ti-6Al-4V, that conforms to the ASTM F136 standard. Screws are 1.5 to 1.8 mm in diameter and range in length from 3 to 6 mm.

Intended Use:

Frontier Devices Neuro System

Frontier Devices Neuro System is intended for use in selective trauma of the cranial skeleton and cranial surgery.

Technology Characteristics

The plates and screws of the Frontier Devices Neuro Closure System have similar dimensions, designs and materials as the predicate devices. The plates are 0.4 and 0.6 mm thick, made from unalloyed titanium (ASTM F67) and have similar design shapes and sizes as the predicate devices. The screws are all made from titanium alloy (ASTM F136) with diameters of 1.5 mm and 1.8 mm and lengths of 3-6 mm which are similar to the predicate devices.

Performance Tests

Screw insertion tests on representative screws showed them to have similar results as predicate screws. In addition, LAL endotoxin testing was done on screws, plates and mesh devices and all the devices had endotoxin levels of less than 0.06 EU/ml.

Substantial Equivalence

The Frontier Devices Neuro Closure System consists of plates and screws that are similar in material composition and have the same indications for use as the predicate device. All of the technical characteristics are substantially equivalent to the corresponding characteristics of the predicate devices. There may be slight differences in dimensions and shapes between the Frontier Devices Neuro Closure System and the predicate devices, however, the information provided in this submission proves substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Folsom Metal Products, Incorporated
153 Cahaba Valley Parkway
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DEC 13 2010

Re: K100205
Trade/Device Name: Frontier Devices Neuro Closure System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: II
Product Code: GWO, HBW, GXR
Dated: November 30, 2010
Received: December 2, 2010

Dear Dr. Peterson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K100205

510(k) Number (if known): 100205

DEC 13 2010

Device Name: Frontier Devices Neuro Closure System

Indications For Use:
The Frontier Devices Neuro System is intended for use in selective trauma of the cranial skeleton and cranial surgery.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100205