K120352

JUN 11 2012

750 Trade Centre Way
Suite 200
Portage, MI 49002
t: 269 324 5346 f: 877 648 7114
www.stryker.com

stryker

Craniomaxillofacial

510(k) Summary of Safety and Effectiveness:

Stryker QuikFlap Sterile Procedure Pack

Proprietary Name:	Stryker QuikFlap Sterile Procedure Pack
Common Name:	QuikFlap Sterile Procedure Pack
Classification Name and Reference:	***Sec. 882.5320*** – Preformed alterable cranioplasty plate ***Sec. 882.5250*** – Burr hole cover ***Sec. 882.5360*** – Cranioplasty plate fastener
Proposed Regulatory Class:	Class II
Product Codes:	GWO – Preformed alterable cranioplasty plate GXR – Burr hole cover HBW – Cranioplasty plate fastener
Predicate Device:	Stryker Universal Neuro 3 system – **K112557**

For Information contact: Jamshed Badarpura
Regulatory Compliance Analyst
Stryker Craniomaxillofacial
750 Trade Centre Way, Suite 200
Portage, MI 49002
Phone: (269) 389-4260
jamshed.badarpura@stryker.com

Date Prepared: 4/5/2012

Intended Use / Indication for Use

The Stryker QuikFlap Sterile Procedure Pack is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).

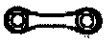
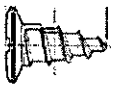
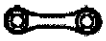
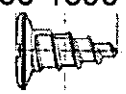
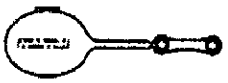
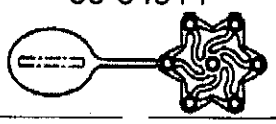
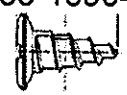
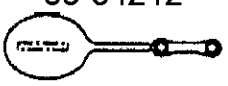
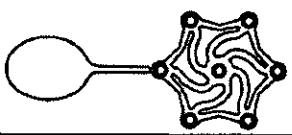
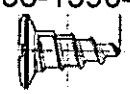
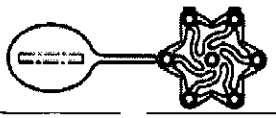
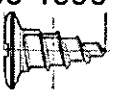
Device Description

The Stryker QuikFlap Sterile Procedure Pack is intended for reconstruction, stabilization and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures. The device can be used in both adults and adolescents (age 12 and higher). Six different procedure packs of Stryker QuikFlap Sterile Procedure Pack will be offered. They consist of different combinations and number of plates and screws. The overview of these combinations is provided in Table 1. All implants which are part of the Stryker QuikFlap Sterile Procedure Pack are also part of the Universal Neuro 3 system. The instruments of the Universal Neuro 3 system are therefore used with the Stryker QuikFlap Sterile Procedure Packs. Universal Neuro 2 products are not contained in the Stryker QuikFlap Sterile Procedure Pack sold in the US.

The Stryker QuikFlap Sterile Procedure Pack is an easy to use implant carrier providing sterile plates, burr hole covers and screws in different groups to allow the use in OR. For a list of the

diverse implants groups provided in Stryker QuikFlap Sterile Procedure Pack please refer to (Table 1).

Table 1: Stryker QuikFlap Sterile Procedure Packs

Description	Stryker ® QuikFlap Article number	Consisting			
		Plates		Screws	
		Article # Neuro III	Amount	Article # Neuro III	Amount
2-HOLE PLATE SET, SELF-DRILLING SCREW	12-01530S	53-36212 	3	56-15904 	6
2-HOLE PLATE SET, SELF-TAPPING SCREW	12-01531S	53-36212 	3	56-15004 	6
2-HOLE PLATE SET, LOW PROFIL WITH TAB	12-01532S	53-34212 	3	56-15904 	6
2-HOLE PLATE/BURR HOLE COVER 14MM SET	12-01534S	53-34212  53-34514 	2 1	56-15904 	10
2-HOLE PLATE/BURR HOLE COVER 20MM SET	12-01536S	53-34212  53-34520 	2 1	56-15904 	10
BURR HOLE COVER 14MM SET	12-01538S	53-34514 	1	56-15904 	6

The implants sold in the Stryker QuikFlap Sterile Procedure Pack are identical in design, material, physical properties and manufacturing process, with the implants of the Universal Neuro 3 system (K112557). The items are based on the same design drawings and are manufactured by the same processes as the implants of Universal Neuro 3 system.

After manufacturing the only difference between the implants sold in the Stryker QuikFlap Sterile Procedure Packs and the Universal Neuro 3 system is the packaging. Here, the Universal Neuro 3 system implants are single packed (plates, burr hole covers) or packed in groups of five (screws in screw rack) into blisters. To provide the surgeon a variety of sterile implants different groups of plates, burr hole covers and screws are packed together into an implant carrier, which is then placed into a blister similar (same material PETG, different size) to the ones used for Universal Neuro 3 system. Pouch is put around the blister of the Stryker QuikFlap Sterile Procedure Pack, and for safety reason this assembly is packed into an additional box, where as the Universal Neuro 3 implants have only a pouch as outer packaging. The Stryker QuikFlap Sterile Procedure Packs are additionally sterilized.

As the implants sold in the Stryker QuikFlap Sterile Procedure Pack are identical with that of FDA cleared Universal Neuro 3 System (K112557) the implants are stated to be safe for implantation. The implants are mechanically safe for implantation, biocompatible, possible to clean and sterilize within the Universal Neuro 3 module and container.

The new aspect of the Stryker QuikFlap Sterile Procedure Pack is the implant carrier. The biocompatibility of the implant carrier was proven including cytotoxicity and GC/MS Fingerprint tests. The handling performance and the transport safety of the whole Stryker QuikFlap Sterile Procedure Pack was determined, so that the new implant carrier of the Stryker QuikFlap Sterile Procedure Pack can be stated as safe and effective for its intended use.

The implant carrier, including the implants, is stored in a blister equal to the ones cleared in the 510(k) for the Universal Neuro 3 System. The blister is made out of the same material (PETG Kodar 6763) by the same supplier in the same process as for the Universal Neuro 3 blister, the only difference is its size. The blister itself is enclosed with the identical Tyvek material. The

safety of the blister –Tyvek – sterile barrier was successfully tested after conditioning of the samples in a transport test. As the blister type is already known and its sealed seam safety was proven by testing the blister, it can be stated as safe for its intended use.

As second sterile barrier, the blister of the Stryker QuikFlap Sterile Procedure Pack is placed in a peel pouch as used for the inlays of the Universal Neuro 3 system. The pouch is therewith a known packaging material which was tested as well for transport safety. A standard box is used as outer packaging. The box passed the transport safety test as well.

Overall following conclusion can be drawn:
The implants sold in the Stryker QuikFlap Sterile Procedure Pack are known and FDA cleared for the Universal Neuro 3 system and are hence proven to be safe and effective in use, biocompatibility, cleaning and sterilization. The new implant carriers were proven to be biocompatible, safe for transportation and efficient for use. Blister, pouch and outer box are known materials that are already in use for Stryker Leibinger products and that are proven to be safe for transportation. So, the Stryker QuikFlap Sterile Procedure Packs can be stated as safe and effective.

Contraindications

- Use of plates in non-reducible and unstable fractures
- Patients with active local infections
- Patients with metal allergies and foreign body sensitivity
- Potentially non-compliant patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions
- Patients with limited blood supply to or insufficient quality of bone
- Use of plates where the fixation of these products could result in their peripheral edge coming into contact with the dura mater.
- Screws coming in contact with the dura mater

- Use of implants adjacent to developing parnasal sinuses

Possible System Adverse Effects

- Metal sensitivities or allergic reaction
- Early or late infection, both deep and/or superficial
- Deformation of affected bone
- Poor implant fixation resulting in mal or nonunion
- Implant breakage resulting in mal or nonunion
- Device migration
- Fibrous encapsulation of implant

Technological Characteristics

Stryker QuikFlap Sterile Procedure Pack is a sterile procedure pack containing bone screws, plates and burr hole covers for the respective anatomical and indicated areas. Different combinations of screws and plates are available in this pack. The surgeon can take out only the implants out of this pack. The offered combinations of screws and plates are adequate to fix common defects. For more complicated cases more than one Stryker QuikFlap Sterile Procedure Pack can be used.

Stryker QuikFlap Sterile Procedure Pack offers an easy, cost-effective solution for cranial flap fixation. Six procedure packs provide surgeons a variety of options for cranial closure. Since the Stryker QuikFlap Sterile Procedure Pack is provided sterile, it can limit processing risks for the hospitals.

The Stryker QuikFlap Sterile Procedure Pack contains bone plates, burr hole covers and screws. The implants are designed for a decreased palpability. The screws are used to fix the plates on bony structures and Stryker custom implants. The contained plates can be bent by hand or by using instruments to have a good fit to the shape of the above mentioned bony structures.

Performance data

This procedure pack is designed in such a way that the surgeon can take out of this pack all the implants he needs for the above mentioned surgeries. For some set configurations (12-01530S, 12-01531S) he can take out the implants needed for every step of the above mentioned surgeries. The packaging and the implant carrier are designed for easy handling of the pack and an easy taking out of the implants.

There are self-drilling and self-tapping screws contained in the Stryker QuikFlap Sterile Procedure Pack. Self-drilling screws can be used without pre-drilling, for self-tapping screws pre-drilling is required. A cross-pin mechanism on the screw head is used for all screws.

In the Stryker QuikFlap Sterile Procedure Pack there are plates with and without tabs. The tab is used to allow an easier handling of the plates. 2-hole plates and burr hole covers are offered in the Stryker QuikFlap Sterile Procedure Pack. The plates have countersinks to allow a secure fit of the screw in the plate. The plates are fixed by form and force fit.

All implants have rounded edges to avoid tissue irritation. All implants are anodized and the corrosion resistance was demonstrated.

Stryker bone plates and bone screws are made of either commercially pure titanium or Ti6Al4V alloy (acc. to ASTM F67, ASTM F136/ISO 5832-3). Both materials are biocompatible according to ISO 10993-1, corrosion-resistant and non-toxic in the biological environment, and produce negligible artefacts on X-ray and CT scans. For the implant carrier Makrolon Rx2530 is used. The packaging material for the blisters is made of PETG ST 3020, the Tyvek out of Tyvek 1073B SBP 2000. The peel pouches are made of STS PA/PE 90 according to ISO 11607.

The Stryker QuikFlap Sterile Procedure Pack along with all the contained implants is offered in double-sealed sterile packaging. All necessary tests were performed to show that these products are clean, there are no cytotoxic effects, and the products and packaging are biocompatible, there is sufficient stability of plates and screws according to ASTM F 382-99 and ASTM F 543, that

this product can be re-sterilized. There are no damages during transport, the implant carrier is sufficiently stable and there is sufficient strength of the seal.

Substantial Equivalence Discussion

The Stryker QuikFlap Sterile Procedure Pack has been verified and validated according to Stryker procedures for product design and development. The validation proves the safety and effectiveness of the system. The subject Stryker QuikFlap Sterile Procedure Pack is substantially equivalent to legally marketed device:

- Stryker Universal Neuro 3 System – K112557

The Stryker QuikFlap Procedure Pack, as stated above, consists of devices with three product codes: GWO (plates), GXR (burr hole covers), and HBW (screws). It has the same material composition and operating principles as its predicate mentioned above. The intended use is identical to the predicate system. Further, there is no difference in dimensions and shapes between the Stryker QuikFlap Sterile Procedure Pack and the predicate device.

Specifically speaking, our Stryker QuikFlap Sterile Procedure Pack plates, burr hole covers and screws are substantially equivalent to Stryker Universal Neuro 3 System (K112557).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker
Mr. Jamshed Badarpura
Regulatory Compliance Analyst
750 Trade Center Way, Suite 200
Portage, MI 49002

JUN 11 2012

Re: K120352
Trade/Device Name: Stryker QuikFlap Sterile Procedure Pack
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO
Dated: May 14, 2012
Received: May 15, 2012

Dear Mr. Badarpura:

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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120352

Device Name: Stryker QuikFlap Sterile Procedure Pack

Indications for Use:

The Stryker QuikFlap Sterile Procedure Pack is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).

Prescription Use X AND/OR Over the counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120352