

DEC 29 2008

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stryker[®]

Instruments

510(k) Summary

Device Sponsor: Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-324-5412

Registration No.: 1811755

Trade Name: Zyphr[™] Disposable Cranial Perforator Bit

Common Name: Cranial Perforator

Classification Name: Drills, Burs, Trephines & Accessories (Compound, Powered) (HBF)

Equivalent to: K892866 Acra-Cut Automatic Cranial Drill (Perforator)
K071931 Codman Disposable Perforator

Device Description: The Zyphr[™] Disposable Cranial Perforator is a mechanically powered tool specifically designed to rapidly create an access hole through the skull in a safe and reliable manner.

Indications For Use: The Stryker Zyphr[™] Disposable Cranial Perforator Large 14/11mm (perforator) is a sterile, single use cutting accessory intended for cutting an 11 mm diameter access hole through the cranium of adult patients. It is intended for thin bone that is at least 3mm thick.

The Stryker Zyphr[™] Disposable Cranial Perforator Small 11/7mm (perforator) is a sterile, single use cutting accessory intended for cutting a 7 mm diameter access hole through the cranium of adult and pediatric patients. It is intended for thin bone that is at least 1mm thick.

Substantial Equivalence (SE) Rational: The Zyphr[™] Cranial Perforator has the same intended use as the **Acra-Cut Automatic Cranial Drill (Perforator)** and **Codman Disposable Perforator**. This device and the predicate devices have the same technological characteristics, the same operating principles, use the same patient contacting materials and have similar performance characteristics.

Safety and Effectiveness: Based upon the comparison to the predicate devices, the Zyphr[™] Cranial Perforator is substantially equivalent to legally marketed devices.

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Submitted by:

Colette O'Connor
Regulatory Specialist

Colette O'Connor

Signature

Date submitted:

22 Dec 08



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2008

Stryker Ireland Ltd.
% Ms. Colette O'Connor
Carrigtwohill Business & Technology Park
Carrigtwohill, Co. Cork
Ireland

Re: K082010

Trade/Device Name: Zyphr™ Disposable Cranial Perforator
Regulation Number: 21 CFR 882.4305
Regulation Name: Powered compound cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBF
Dated: November 7, 2008
Received: November 10, 2008

Dear Ms. O'Connor:

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.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Enclosure

Indications for Use

510(k) Number (if known): K082010

Device Name: Zyphr™ Disposable Cranial Perforator

Indications For Use:

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The Stryker Zyphr™ Disposable Cranial Perforator Small 11/7mm (perforator) is a sterile, single use cutting accessory intended for cutting a 7 mm diameter access hole through the cranium of adult and pediatric patients. It is intended for thin bone that is at least 1mm thick.

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)

David Krone for MxM
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K082010

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