K071931

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510(k) Summary
Codman® Disposable Perforator

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

OCT 2 2 2007

Contact Person

Emily E Valerio
Regulatory Affairs Specialist II
Telephone Number: (508) 828-3038
Fax Number: (508) 828-2777

Name of Device

Proprietary Name:	Codman® Disposable Perforator
Common Name:	Disposable Perforator
Classification Name:	Powered compound cranial drills, burrs, trephines, and their accessories

Device Classification

Powered compound cranial drills, burrs, trephines, and their accessories are Class II devices per 21 CFR § 882.4305 (84 HBF).

Statement of Substantial Equivalence

Codman Disposable Perforators are substantially equivalent to the Codman Disposable Perforator with Hudson End (K791101A) based on the device's similarity to the predicate device in intended use, materials, design, and principles of operations.

Indications for Use

Codman Disposable Perforators are intended to perforate the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.

Physical Description

The Codman Disposable Perforators are pre-assembled, single-use, sterile devices that are designed to perforate the cranium. The perforators consist of a stainless steel inner and outer drill and a stainless steel Hudson End that locks onto a pneumatic or electric driving tool.

Device Testing

Substantial equivalence for this device is based upon comparison to predicate device characteristics and performance testing. Device qualification criteria meet or exceed the minimum qualification criteria for the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Codman & Shurtleff, Inc.
% Ms. Emily E. Valerio
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

OCT 2 2 2007

Re: K071931
Trade/Device Name: Codman Disposable Perforators
Regulation Number: 21 CFR 882.4305
Regulation Name: Powered compound cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBF
Dated: September 13, 2007
Received: September 14, 2007

Dear Ms. Valerio:

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 Office of Compliance at (240) 276-0115. 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,

For Mark N. Melkerson Dep D,R 10/19/07

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

Enclosure

K071931

Indications for Use

510(k) Number (if known):

Device Name: **Codman Disposable Perforators**

Indications For Use:

The CODMAN® Disposable Perforators are indicated for perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.

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 General, Restorative, and Neurological Devices

510(k) Number K071931