

K 933894

DEC 10, 1993

APPENDIX L  
SUMMARY of SAFETY and EFFECTIVENESS INFORMATION

**510(k) Number** K 933894

**Submitted by:** Codman & Shurtleff, Inc.  
41 Pacella Park Drive  
Randolph, MA 02368  
(617) 986-3436

**Contact Person:** Amy Walters

**Date of Report:** July 23, 1993

**Classification Name:** Powered Compound Cranial Drills, Burrs, Trephines, and their Accessories

**Common Name:** Disposable Perforator

**Proprietary Name:** CODMAN Disposable Perforator

**Classification:** 21 CFR 882.4305, Class II

**Device Description:** The CODMAN Disposable Perforator, model number 170640-002, is used to perforate the cranium. These perforations may be required to vent fluid from the cranium, to provide access for surgical instruments, or to provide access for tools used to remove a large skull piece.

The design incorporates an inner drill and an outer drill, designed to disengage automatically when the inner drill penetrates the cranium. The counterbore diameter is 14 mm. The Disposable Perforator is designed to be used with a pneumatic or electric drill.

The CODMAN Disposable Perforator is substantially equivalent to the Codman Disposable Perforator (K791101A), presently marketed by Codman & Shurtleff, Inc., and the Acra-Cut Disposable Perforator (K833266) marketed by Acra-Cut, Inc., Acton, MA.

Test results show that the strength of the shelf left by the outer drill of the Disposable Perforator, model number 170640-002, after disengagement, exceeds the requirements of the proposed ASTM standard for cranial perforators. In addition, the disengagement distance of the inner drill is less than that of the substantially equivalent products cited above. Extensive testing performed with the CODMAN Disposable Perforator 170640-002 has demonstrated that the disengagement mechanism is extremely reliable.

**TABLE 1****Comparison of CODMAN Disposable Perforator Model 170640-002 to Substantially Equivalent Products**

	Codman Perforator 170640-002	Codman Perforator 26-1221 (current model)	Acra-Cut Model 200-253 DGR-11	Acra-Cut Model 200-241 DGR-1
Average Operating Force (lbs)	2.87	5.07	2.40	2.85
Minimum Shelf Fracture Force (lbs)	47.6	76.5	could not be measured (see Appendix K)	55.3
Disengagement Distance (inches)	.047	.70	.62	.62
Power Source	Air Driver or Electric Drill	Same	Same	Same
Load Bearing Component Materials	Stainless Steel & Ultem Thermoplastic	Stainless Steel	Stainless Steel & Aluminum	Stainless Steel & Plastic
Packaging	TYVEK & Blister	Same	Same	Same



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 10 1993

Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850

Ms. Amy Walters  
Regulatory Affairs  
Codman & Shurtleff, Inc.  
41 Pacella Park Drive  
Randolph, Massachusetts 02368-1794

Re: K933894  
Disposable Perforator  
Regulatory Class: II  
Dated: September 24, 1993  
Received: October 4, 1993

Dear Ms. Walters:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) 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 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan, Ph.D.  
Acting Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health