DEC - 8 2003

K032970

510-k Summary

Pursuant to 21 CFR 807.93 the following summary is submitted.

1. Submitter's name-
ACRA-CUT, Inc.
989 Main Street
Acton, MA 01720
1-978-263-0250
Contact Person-Kenneth M. Nicoll
(603) 672-3161

2. Proprietary Name = XPRESS 120
Common Name = Surgical Drill and Perforator

3. We are claiming substantial equivalence to the Osteomed B Power System and the Stryker System II Orthopower 90 Battery Powered Instruments.

4. The ACRA-CUT XPRESS 120 is a battery operated drill that has a skull perforator permanently attached to it. It is for one time use and is delivered charged and sterile.

XPRESS 120 is very similar in how the battery-operated drill operates, is used and in technological characteristics to the Osteomed B Power System and the Stryker System II Orthopower 90 Battery Powered Instruments, except as to where on the body the drill will be used. The XPRESS 120 is intended to be used only in the skull area, while the substantially equivalent products are intended to be used on other parts of the human body, including the skull in the case of the Osteomed product. The XPRESS 120 is also substantially equivalent to the ACRA-CUT perforators already approved, as the submission relates to the perforators themselves. The perforators are identical except that now they are permanently attached to the drill.

5. The ACRA-CUT XPRESS 120 is for use on the skull area only. The device is disposable and for single use only. The device is used to aid the surgeon in perforating the *skull for various types of purposes.*

6. No clinicals were performed with this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2003

ACRA-CUT, Inc.
c/o Mr. Kenneth M. Nicoll
Regulatory Consultant
74 Spring Road
Amherst, New Hampshire 03031

Re: K032970
Trade/Device Name: XPRESS 120
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 5, 2003
Received: September 23, 2003

Dear Mr. Nicoll:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit 3

INDICATIONS FOR USE

510-k Number: No K number yet, new submission. K032970

Device Name: XPRESS 120

Indications For Use:

This device is for use on the skull area only. This device is disposable and for single patient use only. The device is used to aid the surgeon in perforating the skull for various types of purposes. The device does not take the place of the surgeon, it is only a tool to assist the surgeon during the procedure. Decisions about what to do and how to perform a procedure rest firmly with the surgeon.

Prescription Use ✓ 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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032970