K062413

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap Pneumatic Kerrison
August 16, 2006

NOV 2 1 2006

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
800-258-1946 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com

COMMON NAME: Powered rongeur

CLASSIFICATION NAME: Rongeur, Powered

REGULATION NUMBER: 882.4845

PRODUCT CODE: HAD

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Pneumatic Kerrison is substantially equivalent to:

- Aesculap HiLan Motor System by Aesculap Inc. (K980686)
- Aesculap manual Kerrisons by Aesculap Inc. (Class I device)
- Anspach Powered Kerrison System (PKS) by The Anspach Effort, Inc (K022907)

DEVICE DESCRIPTION

The Aesculap Pneumatic Kerrison is powered by pneumatic pressure. The power is supplied by compressed air through luer lock connectors. The compressed air is then transferred into the working direction via an angle lever. The movable sheath pusher moves forward and the punching action is carried out in a two step process.

INDICATIONS FOR USE

Aesculap's Pneumatic Kerrison is intended for removing bone, cartilage and tissue in various surgical disciplines (e.g. neurosurgery and othopaedics).

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Pneumatic Kerrisons are offered in similar operating speeds, power source, and attachments as the predicate devices. The material used for the Aesculap Pneumatic Kerrison is the same or similar as that used to manufacture the predicate devices.

PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system. This device has been evaluated and complies with ASTM F899-95, Standard Specification for Stainless Steel for Surgical Instruments as applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap, Inc.
% Ms. Kathy A. Racosky
Regulatory Affairs Associate
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

NOV 2 1 2006

Re: K062413
Trade/Device Name: Pneumatic Kerrison
Regulation Number: 21 CFR 882.4845
Regulation Name: Powered rongeur
Regulatory Class: II
Product Code: HAD
Dated: October 16, 2006
Received: October 17, 2006

Dear Ms. Racosky:

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,

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

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K062413

Device Name:

Indications for Use:

Aesculap's Pneumatic Kerrison is intended for removing bone, cartilage and tissue in various surgical disciplines (e.g. neurosurgery and othopaedics).

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K062413