APR 2 2 2003

K030556

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
[in Accordance with SMDA of 1990]

Steelex Electrode Set

February 20, 2003

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 2916714

CONTACT: Georg Keller
800-258-1946 x 5073 (phone)
610-791-6882 (fax)

TRADE NAME: Steelex Electrode Set

COMMON NAME: Temporary Pacing Electrode

DEVICE CLASS: Class II

PRODUCT CODE: 74LDF

CLASSIFICATION: 870.3680 – Electrode, Pacemaker, Temporary

REVIEW PANEL: Cardiovascular

INDICATIONS FOR USE

The Steelex Electrode Set is intended for use in temporary cardiac pacing or monitoring.

DEVICE DESCRIPTION

The Steelex Electrode Set comprises a stainless steel 316L braided wire (ASTM-F138), with a plastic isolating cover (Polyethylene). One end of the wire is armed with a stainless steel 420 (ASTM-F899) ½ circle or $^{3}/_{8}$ circle round-bodied needle and the other end is armed with a stainless steel (ASTM-F899) straight needle (break-off). The straight break-off needle also serves as the connection to the generator. The needle sizes for Steelex Electrode Set are available in the USP sizes 302, 420 or 420F, 0, 1-0, 2-0 and 3-0.

PURPOSE FOR SUBMISSION

This submission seeks marketing clearance for Aesculap's Steelex Electrode Set.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Steelex Electrode Set is substantially equivalent to:

- Ethicon, Inc.; Temporary Cardiac Pacing Wire (K980503)
- Medtronic; Model 6494 Unipolar Temporary Myocardial pacing Wire (K012459)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2003

Aesculap®, Inc.
c/o Mr. Georg Keller
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, PA 18034

Re: K030556
Trade Name: Steelex Electrode Set
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular permanent or temporary pacemaker electrode
Regulatory Class: Class II (two)
Product Code: LDF
Dated: February 20, 2003
Received: February 21, 2003

Dear Mr. Keller:

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.

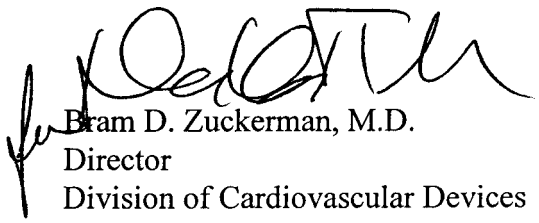
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4646. 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K030556

Device Name: **Steelex Electrode Set**

Indication for Use:

The Steelex Electrode Set is intended for use in temporary cardiac pacing or monitoring.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030556