K081031 page 1/2

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

Endoscopic Clip Applier Line Extension
April 11, 2007

MAY - 5 2008

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

CONTACT: Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)
lisa.boyle@aesculap.com (email)

COMMON NAME: Endoscopic Clip System

CLASSIFICATION NAME: Clips, Implantable

REGULATION NUMBER: *878.4300*

PRODUCT CODE: FZP

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Endoscopic Clip Applier modifications and the addition of the clip magazine are substantially equivalent to the existing components of the Aesculap Endoscopic Clip Appliers (K962493).

DEVICE DESCRIPTION

Aesculap's Endoscopic Clip Appliers consists of two types of clip appliers (multifire (manual) or pneumatic (used CO2 cartridge). The clip appliers are reusable instruments that have either a 5 or 10 mm diameter and range in length from 260mm to 370mm. They are designed for use with a disposable clip magazine which attaches to the shaft of the clip applier. The new clip magazine cartridge hold 8 titanium clips which can be applied one at a time. The instrument handle has a control lever for supplying the clips and a separate control lever for closing the clips. The design enables the surgeon to apply several clips without the need for withdrawing and reinserting the clip applier each time.

INDICATIONS FOR USE

The Endoscopic Clip Appliers with clip magazine are intended for use in endoscopic surgery for ligating, marking vessels and tubular structures in wherever a ligating clip is used/indicated.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The modified clip appliers and the new clip magazine of the Endoscopic Clip Applier System are offered in similar in shapes and sizes as the predicate device. All the components are manufactured from Stainless Steel / Titanium, which is the same material as the predicate devices.

PERFORMANCE DATA

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2008

Aesculap, Inc.
% Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K081031
Trade/Device Name: Endoscopic Clip Appliers with Clip Magazine
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP, GDO
Dated: April 10, 2008
Received: April 11, 2008

Dear Ms. Boyle:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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: K081031

Device Name: Endoscopic Clip Appliers with Clip Magazine

Indications for Use:

The Endoscopic Clip Appliers with clip magazine are intended for use in endoscopic surgery for ligating, marking vessels and tubular structures wherever a ligating clip is used/indicated.

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 K081031