K102081



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

**Endoscopic Clip System**
July 23, 2010

AUG - 6 2010

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

**CONTACT:** Denise R. Adams
800-258-1946 (phone)
610-791-6882 (fax)
denise.adams@aesculap.com (email)

**COMMON NAME:** Endoscopic Clips and Appliers

**CLASSIFICATION NAME:** Clips, Implantable

**REGULATION NUMBER:** *878.4300/870.3250*

**PRODUCT CODE:** FZP/DSS

### SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Endoscopic Clips and Applier modifications are substantially equivalent to the existing components of the Aesculap Endoscopic Appliers and Double Ligating Clips (K080753).

### DEVICE DESCRIPTION

Aesculap's Clip Appliers are reusable stainless steel instruments. The clip appliers can be used in laparoscopic surgery. The clip appliers are available in 12mm diameter with a length of 330mm. The clip appliers are a non-modular, one-piece design for single fire use. These appliers are designed for use with a disposable clip magazine. The new clip magazine cartridge holds 4 clips.

### INDICATIONS FOR USE

The devices presented in this submission are intended for use in endoscopic and/or open surgery for ligating and marking vessels and tubular structures whenever ligating clips are used/indicated.

### TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The new clip appliers and clips of the Endoscopic Clip System are offered in similar 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap®, Inc.
% Ms. Denise R. Adams
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

AUG - 6 2010

Re: K102081
Trade/Device Name: Aesculap Endoscopic Clip Appliers with Disposable Clip Magazine
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: July 23, 2010
Received: July 26, 2010

Dear Ms. Adams:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102081

# Indications for Use

AUG - 6 2010

510(k) Number (if known): K102081

Device Name: Device Name: Aesculap Endoscopic Clip Appliers with Disposable Clip Magazine

Indications for Use:

The devices presented in this submission are intended for use in endoscopic and/or open surgery for ligating and marking vessels and tubular structures whenever ligating clips are used/indicated.

Prescription Use __X__ 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices



510(k) Number K102081