SEP 30 1998

K98 2623

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

AESCULAP NEEDLESCOPIC INSTRUMENT SYSTEM

July 27, 1998

Company

Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080

Contact

Lia S. Jones, Regulatory Associate
Phone: 650-876-7000 x 350
FAX: 650-589-3007

Trade Name

Aesculap Needlescopic Instrument System (N.I.S.)

Common Name

Endoscope and Accessories

Classification Name and Product Code

78KOG Endoscope and/or Accessories

Product Classification

Class II

Regulatory Classification

21 CFR Section 876.1500

Intended Use

The Aesculap Needlescopic Instrument System (N.I.S.) is indicated for use in adult and pediatric diagnostic and therapeutic general endoscopy and laparoscopy surgery.

Device Description

The system consists of three primary components: a 2.5mm trocar, a 2.0mm endoscope, and 2.5mm modular instruments. The N.I.S. trocar is intended to establish ports through which endoscopes and endoscopic instruments pass into the abdominal cavity. The N.I.S. endoscope is used to examine body cavities, hollow organs and canals, and using additional accessories, to perform various diagnostic and therapeutic procedures. The N.I.S. instruments are used to cut, manipulate, grasp and/or cauterize selected tissue.

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Summary of Technological Characteristics

Aesculap currently markets a complete endoscopic product line which includes endoscopes and modular trocars and instruments. The Needlescopic Instrument System does not impart any new technological characteristics from the current system other than the reduction in diameter size of the devices.

Performance Data

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the instruments in Aesculap's Needlescopic Instrument System that are intended for electrosurgery meet the requirements of IEC 601-2-18, the International Electrotechnical Commission Standard for Electrosurgical Devices.

Substantial Equivalence

Aesculap believes that the Needlescopic Instrument System presented in this submission is substantially equivalent in design, function, and intended use to currently marketed endoscopic systems, such as:

- **Aesculap Endoscopy Instruments**
  by Aesculap (#K942053, #K941239, #K942730, #K940936))
- **MicroLap System**
  by Imagyn Medical Inc. (#K965055)
- **Miniature Laparoscope Set (Mini Lap)**
  by Richard Wolf GMBH (#K962799)
- **KOH Micro-Suturing Instruments**
  by Karl Storz Endoscopy-America, Inc. (#K955479)
- **Semi-Rigid Micro Endoscopes and Accessories for Adult and Pediatric General Endoscopic and Laparoscopic Surgery**
  by Karl Storz Endoscopy-America, Inc. (#K946164)
- **Minisite 2mm Microlaparoscopy System**
  by United States Surgical Corporation (#K972415)
- **Micro-L Laparoscopy System**
  by Circon Corporation (#K unknown)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1998

Ms. Lia S. Jones
Regulatory Associate
Aesculap®, Inc.
1000 Gateway Boulevard
South San Francisco, California 94080

Re: K982623
Trade Name: Aesculap Needlescopic Instrument System (N.I.S.)
Regulatory Class: II
Product Code: GCJ
Dated: July 27, 1998
Received: July 28, 1998

Dear Ms. Jones:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K982623

Device Name: **Aesculap Needlescopic Instrument System**

Indication for Use:

Aesculap's Needlescopic Instrument System (N.I.S.) is indicated for use in adult and pediatric diagnostic and therapeutic general endoscopy and laparoscopy surgery.

(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 Devices
510(k) Number K982623

Prescription Use ✓ or Over-the-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)