510(k) SUMMARY K061135

JUL 11 2006

A. Submitter Information:

Submitter:	Aesculap, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Tel: (610) 984-9072 Fax: (610) 791-6882
Contact:	Matthew M. Hull Regulatory Affairs Manager
Date Prepared:	11 April 2006

B. Trade Name: MINOP® Disposable Introducer
Common Name: Endoscope Introducer
Classification: GYK
C.F.R. Section: 882.4545
Class: II

C. Predicate Devices:

K022513 Medcomp Vascu-Sheath® Introducer Set
K990333 Medtronic PS Medical Endoscope Introducer

D. Device Description:

The MINOP® Disposable Introducer is a single use device used to obtain ventricular access and facilitate endoscope insertion. The MINOP® Disposable Introducer consists of an introducer sheath and a ventricular obturator.

E. Intended Use:

The MINOP® Disposable Introducer is indicated to obtain and maintain a temporary pathway into the ventricular system of the brain.

F. Comparison to Predicate Device:

The technological characteristics of the MINOP® Disposable Introducer are substantially equivalent to the predicate devices. The proposed device is equivalent to the Medcomp Vascu-Sheath® Introducer Set in terms of design, materials, performance and sterilization; while the only differences are the indications for use, the obturator of the proposed device has a rounded tip, and its sheath has ink depth markings. The proposed device is equivalent to the Medtronic PS Medical Endoscope Introducer in regard to the indications for use.

G. Performance Data:

Performance testing was performed on the peel force of the sheath for the Medcomp Vascu-Sheath® predicate device; the only sheath design change between this device and the proposed device is the addition of ink depth markings, which do not affect the peel force of the sheath. The rounding of the obturator tip on the proposed device also has no bearing on the peel force of the sheath. All other aspects of the obturator and

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sheath are identical to the legally marketed Medcomp device. Results of the peel force testing meet the requirements defined in Medcomp's internal standards for force at break.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2006

Aesculap, Inc.
% Medcomp
Ms. Lisa Weikert
Regulatory Specialist
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K061135
Trade/Device Name: MINOP® Disposable Introducer
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: II
Product Code: GWG
Dated: June 13, 2006
Received: June 14, 2006

Dear Ms. Weikert:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K061135

Device Name: MINOP® Disposable Introducer

Indications for Use:

THE MINOP® DISPOSABLE INTRODUCER IS INDICATED TO OBTAIN AND MAINTAIN A TEMPORARY PATHWAY INTO THE VENTRICULAR SYSTEM OF THE BRAIN.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K061135