

K 973621

XIII. Kit Certification Statement

DEC 17 1997

The Reusable Clamp or the Single-Use catheter will not be sold as part of any kits.

XIV. Summary Of Safety And Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's "510(k) 'SE' Decision Making Process Documentation" and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: PRE-VIEW* Cholangiography Clamp

PREDICATE DEVICE NAME: ENDOPATH* Cholangiography Clamp
K 942450

510(k) "SE" DECISION-MAKING PROCESS

INDICATIONS STATEMENT: YES. The New Device and the ENDOPATH* Cholangiography Clamp Predicate Device have identical indications for use. The two devices, in fact, are the same instrument.

INDICATED USE: YES. The New Device and the ENDOPATH* Cholangiography Clamp are designed to grasp and introduce contrast medium into the gallbladder for evaluation of stones, blockage and/or other abnormalities. Both of these devices are intended for use in either minimally invasive or open surgical procedures.

TECHNOLOGICAL CHARACTERISTICS: YES. The technological characteristics of the New Device are the same as the Predicate Device. Both of these devices are manually activated surgical instruments.

DEVICE CHARACTERISTICS: The PRE-VIEW* Cholangiography Clamp just like the ENDOPATH* Cholangiography Clamp consists of a 5mm clamp with a side channel for the introduction of a catheter. It is a hand held manual instrument designed for grasping and introducing contrast medium for cholangiography.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

S.S. Kumar, M.D.
President
Nashville Surgical Instruments
322 Northcrest Drive
Springfield, Tennessee 37172

Re: K973621
Trade Name: PRE-VIEW* Cholangiography Clamp
Regulatory Class: II
Product Code: KOG
Dated: September 19, 1997
Received: September 23, 1997

Dear Dr. Kumar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is 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 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.

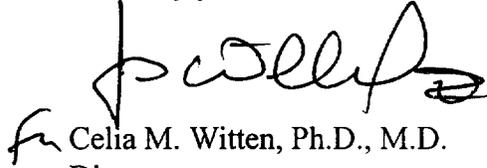
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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 device 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.

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This letter will allow you to begin marketing your device as described in your 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 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 device, 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "M".

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

510(k) Number (if known): K973621

Device Name: Pre-View Cholangiography Clamp

Indications For Use:

The Pre-View Cholangiography Clamp is intended to provide a method of laparoscopic cholangiography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973621

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)