JUN 23 1999

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K991548

510(K) SUMMARY
HAL SCOPE HOLDER SYSTEM

Date: April 9,1999

Owner/Operator: Noved Medical , Inc.

Contact Person: Mike Griffin
Vice President of Operations
Noved Medical, Inc.

Device Trade Name: HAL Scope Holder System

Common Name: Surgical Drape

Classification Name: Surgical Drape and Drape Accessories

Regulatory Reference : 79KKX

Predicate Device: Hydromed Product's Universal Drape

Description:

The HAL Scope Holder System is used to provide a sterile barrier for re-usable manipulating arm. The disposable cover includes a sterile quick release scope adapter and sterile drape assembly. The device will be installed to an existing re-usable manipulating arm before a medical procedure to act as a barrier between the sterile field and the non-sterile re-usable manipulating arm. The device is single use only and can be used with Noved Medical Universal Arm.

Intended Use:

The HAL Scope Holder System is intended for use during a medical procedure where sterile barrier is required on manipulating / movable arms.

Physical/Technical Comparison:

Technological Comparison: The Noved HAL Scope Holder System is technologically equivalent to the drape marketed by Hydromed Products based on the following:

a) Similarity of Materials: Noved Medical drapes are constructed primarily of polyethylene film heat sealed to a tip attachment.

b) Construction: The predicate device and the HAL Scope Holder System are constructed using heat sealed polyethylene film.

c) Packaging: The HAL Scope Holder System are packaged in form, peel and seal pouches and is sterilized through Gamma sterilization. Both the new device and the predicate device maintain a sterilization assurance level of 10^{-6} SAL.

Performance Data:

Non-Clinical Evaluations: Based on appearance and handling evaluations, the HAL Scope Holder System is similar to the predicate device.

Clinical Evaluation: Based on the strength and elongation of the polyethylene film used in the HAL Scope Holder System, the material used for the new device was determined to be acceptable. (Data for the predicate device is not available).

Barrier testing was determined not to be applicable for the HAL Scope Holder System. Determination was made after reviewing the Biocompatibility Flow Chart (matrix) included in ISO-10993 guidelines memo dated May 1, 1995.

Conclusion: Based on all physical performance comparisons, the HAL Scope Holder System will function effectively and comparable to the Universal Camera Drape marketed by Hydromed Products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Mike Griffin
Vice-President of Operations
Noved Medical, Incorporated
168 Avenida Del Mar, Suite 120
San Clemente, California 92672

Re: K991548
Trade Name: HAL™ Scope Holder System
Regulatory Class: II
Product Code: KKX
Dated: April 9, 1999
Received: May 3, 1999

Dear Mr. Griffin:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991548

Device Name: HAL Scope Holder System

Indication For Use:

The HAL Scope Holder System is intended for use during medical procedure where sterile barrier is required on manipulating/ movable arms.

It is for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use X

(Per CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991548