JAN 12 1998

K973543

510(K) SUMMARY

as required by 807.92(c)

KRONNER PROTOTYPES, INC.

1443 Upper Cleveland Rapids Road
Roseburg, Oregon 97470
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Prepared: September 8, 1997

Contact Person: Crystal Kronner, Secretary

Trade Name: **Kronner Low Profile Scope Holder**

Common Name: **Endoscope Holder**

Classification Name: **Endoscope holding device,**
(no industry name for this device)

Equivalent to legally marketed devices

by

(K951854) Leonard Arm

Description:

The Kronner Low Profile Scope Holder consists of mechanical linkages that connect between the operating table side rail and the shaft or head of a rigid endoscope. A telescoping arm distinguishes the device from other endoscope holders. Inert nitrogen gas at 100-150 psi is used to provide the energy to multiple joints to lock the holder in position when a control button is released by the operator.

Intended Usage:

The Kronner Low Profile Scope Holder is used to hold rigid endoscopes during endoscopic surgery and to allow rapid position changes by the pressing of a control button by the operator.

Summary of technological characteristics of device compared to predicate devices.

The Kronner Low Profile Scope Holder is essentially equivalent to the Leonard Arm, except that it has a telescoping arm instead of an arm with a hinge joint, and uses nitrogen gas pressure as an energy source to hold position rather than vacuum.

The Kronner Low Profile Scope Holder uses flexible lines and a control which can be attached to the camera to supply and control the energy used to lock the joints. These features are built into the Leonard Arm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Ms. Crystal Kronner
Secretary
Kronner Prototypes, Incorporated
1443 Upper Cleveland Rapids Road
Roseburg, Oregon 97470

Re: K973543
Trade Name: Kronner Low Profile Scope Holder
Regulatory Class: II
Product Code: GCJ
Dated: December 11, 1997
Received: December 29, 1997

Dear Ms. Kronner:

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.

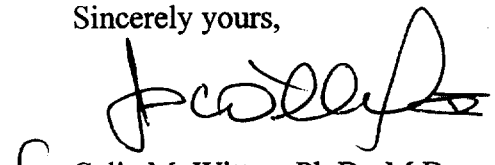
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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,



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

Indications For Use:

KLH-100 Kronner Low Profile Scope Holder
For abdominal, thoracic, arthroscopic and nasal endoscopic surgical procedures.

HPL-2-30 High pressure flexible gas line set, double output
For abdominal, thoracic, arthroscopic endoscopic surgical procedures.

HPL-3-30 High pressure flexible gas line set, triple output
For nasal endoscopic surgical procedures.

KLH-200 Arm assembly
For abdominal, thoracic, arthroscopic and nasal* endoscopic surgical procedures.

*requires the Small Endoscope Accessory

C-100 Arm assembly
For abdominal, thoracic, arthroscopic and nasal endoscopic surgical procedures.

C-101 Control strap, replacement
For abdominal, thoracic, arthroscopic and nasal endoscopic surgical procedures.

SG-101 Scope grip strap, replacement
For abdominal, thoracic, arthroscopic and nasal endoscopic surgical procedures.

SMA-100 Small Endoscope Accessory
For nasal endoscopic surgical procedures

(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 K973543

Prescription Use X OR Over-The-Counter Use_____
(Per 21CFR 801.109)