DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

Kronner Prototypes, Inc.
Richard F. Kronner, M.D.
President
1443 Upper Cleveland Rapids Road
Roseburg, OR 97470

Re: K000663
Trade/Device Name: Low Profile Scope Holder
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated (Date on orig SE ltr): February 22, 2000
Received (Date on orig SE ltr): February 28, 2000

Dear Dr. Kronner,

This letter corrects our substantially equivalent letter of May 2, 2000.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): _____K000663_____

Device Name: Kronner Low Profile Scope Holder

Indications for Use:

KSH-4 Kronner Low Profile Scope Holder
For abdominal and thoracic endoscopic surgical procedures

HPL2-CRL High pressure* Gas Line Set
For abdominal and thoracic endoscopic and arthroscopic surgical procedures

KSHSA-3 Standard Arm Assembly
For abdominal and thoracic endoscopic surgical procedures

C-1 Control
For abdominal, thoracic, arthroscopic, endoscopic surgery and holding manual surgical instruments

ECB-2 Electronic Control Box
For abdominal, thoracic, arthroscopic, nasal endoscopic surgical procedures and holding manual surgical instruments

GLW-1 Gas line wrench
For abdominal, thoracic, arthroscopic, nasal endoscopic surgical procedures and holding manual surgical instruments

SEAH-1 Small Endoscope Accessory with Handle
For nasal endoscopic surgical procedures

HPL1-BL1-CRL High pressure* Branched Gas Line Set
For nasal endoscopic surgical procedures and holding manual surgical instruments

* Tolerates pressures to 150 PSI, do not use with pressures over 150 psi.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon
(Division Sign-Off)
Division of Restorative Devices
510(k) Number K000663

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

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(Optional Format 1-2-96)

MAY - 2 2000

K 000663

510(K) SUMMARY
as required by 807.92(c)

K000663

KRONNER PROTOTYPES, INC.
1443 Upper Cleveland Rapids Road
Roseburg, Oregon 97470
Phone: (541) 672-2543
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E-mail: kronner@rosenet.net

Prepared: February 22, 2000

Contact Person: Richard Kronner, President

K000663

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

Common Name: **Endoscope Holder**

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

K000663

Equivalent to legally marketed devices

by

(K973543) Kronner Prototypes, Inc.

K000663

Description:

The Kronner Low Profile Scope Holder with Electronic Control and Control Box is the same as the Kronner Low Profile Scope Holder (K973543) with mechanical control except that it has an electronic control, momentary button, and electronic control box with solenoids to control gas output.

K 000663

Intended Usage:

KSH-4 Kronner Low Profile Scope Holder
For abdominal and thoracic endoscopic surgical procedures

HPL2-CRL High pressure* Gas Line Set
For abdominal and thoracic endoscopic and arthroscopic surgical procedures

KSHSA-3 Standard Arm Assembly
For abdominal and thoracic endoscopic surgical procedures

C-1 Control
For abdominal, thoracic, arthroscopic, endoscopic surgery and holding manual surgical instruments

ECB-2 Electronic Control Box
For abdominal, thoracic, arthroscopic, nasal endoscopic surgical procedures and holding manual surgical instruments

GLW-1 Gas line wrench
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SEAH-1 Small Endoscope Accessory with Handle
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For nasal endoscopic surgical procedures and holding manual surgical instruments

* Tolerates pressures to 150 PSI, do not use with pressures over 150 psi.

K000663

Summary of technological characteristics of device compared to predicate devices.

The Kronner Low Profile Scope Holder with Electronic control and Electronic Control Box is essentially equivalent to the Kronner Low Profile Scope Holder (K973543) except that the mechanical control has been replaced with an electronic control and electronic control box with solenoids to control gas output.