

K101810



AUG 30 2010

6. 510(k) Summary

510(k) Summary for
The Viking 3DHD Video Camera System

According to the requirements of 21CFR 807.92, the following information provides sufficient detail to understand the basis for determination of substantial equivalence.

**Submitter Name, Address,
and Contact Information:**

Christine Nichols RAC
Regulatory Manager
Vision Systems Group
A Division of Viking Systems Inc.
134 Flanders Road
Westboro, MA 01581
Ph: 508-366-3668 X8273

Device Name and Classification:

Proprietary Names:

3DHD Video Camera System

Classification name:

Endoscope and/Or Accessories, 21CFR 876.1500

Common/Usual names:

Endoscope and Accessories, KOG

Predicate Devices:

K021290 Visualization System
K081585 3 Chip Endoscopy System

Device Description:

The Viking 3DHD Video Camera System consists of camera heads, 3D endoscopes, and a camera controller.

The system can be used with commercially available light sources, light cables, 2D endoscopes, couplers, and 2D and 3D video monitors or head mounted displays.

Intended Use:

The 3DHD Video Camera System is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required.

Indications for Use:

For use in all types of video assisted minimally invasive procedures including: general surgery, gynecologic, thoracic, urologic, bariatric, spinal, ENT and as an aid in visualization of cardiac structures.

Substantial Equivalence Information:

The proposed 3DHD Video Camera System is substantially equivalent to the currently legally marketed Visualization System (K021290) and the 3 Chip Endoscopy System (K081585) in terms of intended use, operating principle, and basic design. Testing demonstrates that the modifications proposed herein do not adversely effect safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Christine E. Nichols, RAC
Regulatory Manager
Vision Systems Group
A Division of Viking Systems, Inc.
134 Flanders Road
WESTBORO MA 01581

AUG 30 2010

Re: K101810
Trade/Device Name: Viking 3DHD Video Camera System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: June 28, 2010
Received: June 29, 2010

Dear Ms. Nichols:

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.

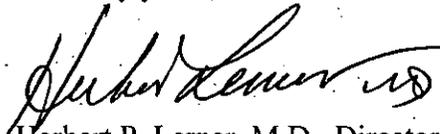
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

5. Indications for Use Statement

Indication for Use

510(k) Number (if known): K101810

Device Name: Viking 3DHD Video Camera System

Indications For Use:

For use in all types of video assisted minimally invasive procedures including: general surgery, gynecologic, thoracic, urologic, bariatric, spinal, ENT and as an aid in visualization of cardiac structures.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K101810