Medical Technologies

7) 510(k) Summary

K021290

510(k) Summary for Vista Visualization System

A. Sponsor

Vista Medical Technologies
134 Flanders Road
Westborough, MA 01581

B. Contact Name

Graham A. L. Baillie
Manager,
Quality Assurance and Service
Vista Medical Technologies
Phone: (508) 366-3668 ext. 8279
Facsimile: (508) 366-8858

C. Device Name

Vista Visualization System

D. Predicate Device(s)

Vista StereoScope System (K020301); Head Mounted Display System (K973436); ORPC with Infomatix IntraOp Software (K991303).

E. Device Description

The Vista Visualization System is used to allow observation in body cavities, organs, or canals through manmade or natural orifices. It is designed for use in all types of endoscopic and endoscopic assisted procedures including bariatric surgeries. The system consists of the Vista StereoScope System (camera head, endoscope and a camera control unit), and the Head Mounted Display System (HMD with HMD processor). The system is designed to work with commercially available light sources, light guides, and video monitor displays.

F. Intended Use

The Vista Visualization System is intended for the use in endoscopic procedures and all types of video assisted procedures, including general endoscopic and laparoscopic, bariatric, thoracic, anterior and posterior spinal and as an aid in visualization of cardiac structures.

G. Substantial Equivalence

The proposed Vista Visualization System is substantially equivalent to the currently legally marketed Vista devices in terms of intended use, operating principle, basic design, and shelf life. The addition of a specific indication for bariatric surgery does not affect the intended diagnostic affect or safety and effectiveness.

Vista Medical Technologies

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2002

Mr. Graham Baillie
Vista Medical Technologies, Inc.
134 Flanders Road
Westborough, Massachusetts 01581

Re: K021290
Trade/Device Name: Vista Visualization System, Model 9000
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 22, 2002
Received: April 23, 2002

Dear Mr. Baillie:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9) Indications for Use Statement

Statement of Intended Use

510(k) Number (if Known): K021290

Device Name: **Vista Visualization System**

Indications For Use:

The Vista Visualization System is intended for use in endoscopic procedures and all types of video assisted procedures, including general endoscopic and laparoscopic, bariatric, thoracic, anterior and posterior spinal and as an aid in visualization of cardiac structures

(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**
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021290