510(K) SUMMARY

FEB - 8 2011

Sponsor/Submitter:	Vibrynt, Inc. 701 Galveston Dr. Redwood City, CA 94063
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Date Summary was Prepared:	February 4, 2011
Device Trade Name	VISTA™ Endoscope SCOUT™ Blunt-tipped Guide
Device Common Name:	Endoscope and accessories
Device Product Codes and Classification Names:	GCJ, Class II Endoscope and accessories (21 CFR 876.1500)
Predicate Devices:	Olympus Laparo-Thoraco Videoscope (K053382) Hans Hermann Laparoscopes and Accessories (K051610) Acclarent MicroEndoscope (K063078)
Device Description:	The VISTA Endoscope is a flexible fiberscope that allows for visualization of the thoracic and abdominal cavities. The device is labeled non-sterile and must be sterilized prior to use. The Endoscope may be used with or without the SCOUT™ Blunt-tipped Guide accessory, which aids in Endoscope advancement and steerability. The Guide also has a fluid channel (cannula) that may be used to deliver saline that may be required for irrigation during an endoscopic procedure. The SCOUT™ Guide is a sterile, single-use device, sterilized by electron beam radiation.
Indications for Use:	The VISTA™ Endoscope and accessories are intended for use in providing access to, and visualization of, the thoracic and abdominal cavities, to allow for the performance of various diagnostic and therapeutic surgical procedures.

510(K) SUMMARY

Technological Characteristics:

The VISTA Endoscope contains illumination and image fibers that transmit an image from the distal to the proximal end of the device. The image may be viewed through the eyepiece or by attaching a standard endoscopic camera and viewed using a video monitor. The Guide's transparent polycarbonate tip enables visibility during the procedure, while the flexible PVC sheath and adjustable stylet increase steerability and support for difficult-to-reach anatomy. The table below compares the technological characteristics of the VISTA Endoscope to those of the predicate devices.

Attribute	Subject Device VISTA Endoscope	Predicate Device (Olympus Laparo-Thoraco Videoscope XLTF-VAW)	Predicate Device (Hans Hermann Laparoscopic Instruments)	Predicate Device (Acclarent MicroEndoscope)
Indications for Use	The VISTA Endoscope and accessories are intended for use in providing access to, and visualization of, the thoracic and abdominal cavities, to allow for the performance of various diagnostic and therapeutic surgical procedures.	This instrument has been designed . . . for endoscopic observation, diagnosis and treatment within the thoracic and abdominal cavities, including female reproductive organs.	The laparoscopes and accessories are intended for use in providing access to and visualization of body cavities, organs, and canals to perform various diagnostic and therapeutic surgical procedures.	The MicroEndoscope is intended to provide an endoscopic means to view a body cavity for ear, nose, or throat procedures.
Materials potentially contacting patient	Stainless steel, glass, epoxy EP42HT-2, blue ultem, polyimide, Pebax	Not Known	Surgical grade stainless steel, PTFE, PEEK, several coatings, silicon and brass chromium plated	stainless steel, gradient image glass, epoxy EP42HT-2, black ultem, polyimide, polyolefin
Rigidity	Flexible	Semi-rigid	Rigid	Semi-rigid
Viewing Optics	Coherent Fiber	Electronic Video CCD	Rigid rod-lens	Coherent Fiber
Number of Pixels	50,000	N/A	N/A	10,000
Depth of Field	5mm – infinity	15-100 mm	Not known	3-25 mm
Field of View	70°	80° -90°	Not known	70°
Direction of View	0° (forward Viewing)	0° (forward Viewing)	0°,30 °, 45°, 70 °	70°
Outer Diameter of Distal End	5.0 mm	5.4 - 10.5 mm	5-10 mm	0.9 mm

510(K) SUMMARY

Attribute	Subject Device VISTA Endoscope	Predicate Device (Olympus Laparo-Thoraco Videoscope XLTF-VAW)	Predicate Device (Hans Hermann Laparoscopic Instruments)	Predicate Device (Acclarent MicroEndoscope)
Jacket Material	Pebax	Not Known	Stainless steel	Polyimide
Working Length	56.4 – 109.7 cm	33.0 – 37.0 cm	30.0-33.0 cm	60.9 cm

Performance Data: Laboratory and performance tests were executed to ensure that the devices functioned as intended and met design specifications. Data demonstrated that the VISTA Endoscope and accessories met all performance testing acceptance criteria and comply with the following standards / guidance documents:

- EN 60601-2-18: 1996, *Medical Electrical Equipment Part 2: Particular requirements for the safety of endoscopic equipment* and the corresponding general standard, EN60601-1:1990 *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- ISO 10993-1:2003, *Biological evaluation of medical devices – Part 1: Evaluation and testing*
- AAMI TIR12:2004 – *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers* (VISTA Endoscope)
- ISO 11137:2006, *Sterilization of health care products – Radiation (parts 1 and 2)* (SCOUT Guide)

Conclusions: When compared to the predicate devices, the VISTA Endoscope and accessories do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Vibrynt, Inc.
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Redwood City, California 94063

FEB - 8 2011

Re: K100533
Trade/Device Name: VISTA™ Endoscope; SCOUT™ Blunt-tipped Guide
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 01, 2011
Received: February 03, 2011

Dear Ms. Anastas:

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" (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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100533

Trade Name: VISTA™ Endoscope
SCOUT™ Blunt-tipped Guide

Common Name: Endoscope and Accessories

Indications For Use: The VISTA™ Endoscope and accessories are intended for use in providing access to, and visualization of, the thoracic and abdominal cavities, to allow for the performance of various diagnostic and therapeutic surgical procedures.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100533