

3/30/99

K990860

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

Classification: Class II
Image Assisted Surgery Device

Common/Usual Name: Image Assisted Surgery Device Option

Proprietary Name: ViewPoint Passive Tool Option

Establishment Registration: Picker International, Inc.
World Headquarters
595 Miner Road
Highland Heights, Ohio 44143
Contact: Elaine K. Keeler, Ph.D.
Phone Number: (440) 473-3000

FDA Owner Number: #1580240
FDA Registration Number: #1525965

Performance Standards: No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The ViewPoint Passive Tool Option does not change the existing intended use and indications for use for the ViewPoint as defined below.

The ViewPoint is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.

The ViewPoint is indicated for use in:

- Intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous)
- Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms.

3. Device Description

The Passive Tool Option for the ViewPoint system allows for optical tracking of wireless tools. The position sensor assembly provided with this option emits an infrared signal that is reflected off reflective markers mounted on the tools.

4. Safety and Effectiveness

The ViewPoint system with the Passive Tool Option is substantially equivalent to the ViewPoint system described in the 510(k) submission K970604. The following chart has been compiled to demonstrate this substantial equivalency.

Substantial Equivalence Chart

Parameter	ViewPoint Passive Tool Option	Predicate Device - ViewPoint 3.0 Software (K970604)
Tools	A long and short wireless tool with a minimum of three reflective markers per tool.	A long and short tool with a minimum of four IREDs per tool.
Average Tool Accuracy	Same.	2.0 - 5.0 mm
Type of Detector	Infrared signals emitted from the Position Sensor Assembly (PSA) are reflected off of reflective markers mounted on the tool. The reflected signal is detected by the PSA with two optical detectors. The assembly is either on a mobile pedestal, mounted to the OR table or mounted to the ceiling.	Infrared signals emitted from diodes on a hand-held tool are detected by a Position Sensor Assembly with two optical detectors. The assembly is either on a mobile pedestal, mounted to the OR table or mounted to the ceiling.
Active Digitizer Volume	Same.	Silo shape comprised of 0.5m radius hemisphere and a cylinder with 0.5m radius and 0.5m length. Detector Positioning Feature added to guide user in finding center of active digitizer volume.
Registration Technique	Same.	Scanned Fiducials and Anatomical Fiducials.
Operating Software Structure	Same.	UNIX environment with three major processes: Import, Surgery Application and Foot Switch. Uses a Graphical User Interface to facilitate interaction with user.
Image Manipulation	Same.	MPR and surface rendering.
Other Features	Same.	Detector Positioning Feature.

Parameter	ViewPoint Passive Tool Option	Predicate Device - ViewPoint 3.0 Software (K970604)
Intended Use	Same.	The ViewPoint is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.
Indications for Use	Same.	The ViewPoint is indicated for use in: <ul style="list-style-type: none"> ▪ Intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous) ▪ Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms.



MAR 30 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
595 Miner Road
Highland Heights, Ohio 44143

Re: K990868
Trade Name: ViewPoint Passive Tool Option
Regulatory Class: II
Product Code: HAW
Dated: March 12, 1999
Received: March 16, 1999

Dear Dr. Keeler:

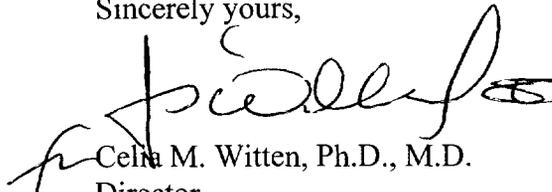
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 requirement, 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

510(k) Number (if known): K990868

Device Name: ViewPoint Passive Tool Option

Indications for Use:

The ViewPoint Passive Tool Option does not change the existing intended use and indications for use for the ViewPoint as defined below.

The ViewPoint is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.

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(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: **General Restorative Devices**

510(k) Number K990868

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)