K970604

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

MAY 19 1997

1. General Information

Classification:	Class II Image Assisted Surgery Device
Common/Usual Name:	Image Assisted Surgery Device Option
Proprietary Name:	ViewPoint - 3.0 Operating Software
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 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. The device does comply with the draft voluntary industry standard titled "Neurological Standard for Image-Interactive Stereotactic and Localization Systems (ASTM 10th Draft 9/94)."

2. Intended Use and Indications for Use

The intended use of the ViewPoint is unchanged by the 3.0 software, but the indications for use have been expanded to include spinal surgical procedures. The intended use and indications for use are as follows:

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 new features in the 3.0 Software include a detector positioning feature and support for the following optional hardware accessories: a tracking device, drill guides and a CT spine phantom. The indications for use of the ViewPoint have also been expanded to include use in spinal surgeries.

4. Safety and Effectiveness

The ViewPoint System operating with the 3.0 software is substantially equivalent to the ViewPoint System described in the 510(k) submissions K961168 and K963221. The following chart has been compiled to demonstrate the substantial equivalence of the ViewPoint operating with the 3.0 software to the predicate device.

SUBSTANTIAL EQUIVALENCE CHART

Parameter	Predicate Device ViewPoint & Optical Digitizer Option (K961168, K963221)	ViewPoint with 3.0 Software
Tools	A long and short tool with a minimum of four IREDs per tool. (See K963221)	Same.
Average Tool Accuracy	2.0 - 5.0 mm (See K961168)	Same.
Type of Detector	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. (See K963221)	Same.
Active Digitizer Volume	Silo shape, with 1 meter diameter and 1 meter length. (See K963221)	Same, Detector Positioning Feature added to guide user in finding center of active digitizer volume.
Accessories	MR/CT Head Phantoms. (See K961168)	MR/CT Head Phantoms, CT Spine Phantom, Tracking device, Drill Guide.

Parameter	Predicate Device ViewPoint & Optical Digitizer Option (K961168, K963221)	ViewPoint with 3.0 Software
Registration Technique	Scanned Fiducials. (See K961168)	Scanned Fiducials and Anatomical Fiducials.
Operating Software Structure	UNIX environment with three major processes: Import, Surgery Application and Foot Switch. Uses a Graphical User Interface to facilitate interaction with user.	Same structure. Modified Graphical User Interface with similar functionality.
Image Manipulation	MPR and surface rendering.	Same.
Other Features	None. (See K961168)	Detector Positioning Feature.
Intended Use	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. (See K961168)	Same.
Indications for Use	The ViewPoint is indicated for use in intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous). (See K961168)	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1997

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
5500 Avion Park Drive
Highland Heights, Ohio 44143

Re: K970604
Trade Name: ViewPoint - 3.0 Operating Software
Regulatory Class: II
Product Code: 84HAW
Dated: February 14, 1997
Received: February 18, 1997

Dear Dr. Keeler:

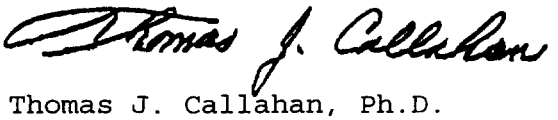
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K970604

Device Name: ViewPoint - 3.0 Operating Software

Indications for Use:

The intended use of the ViewPoint is unchanged by the 3.0 software, but the indications for use have been expanded to include spinal surgical procedures. The intended use and indications for use are as follows:

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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)

Thomas J. Callahan

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[illegible]diovascular, Respiratory,
Devices

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