JUL 8 1999

K983764

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 Tools - Sterrad
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.

2. Intended Uses

The ViewPoint is intended for use as a device that 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

Prior to use the ViewPoint tools must be sterilized. Testing has been completed to validate the use of the Sterrad 100 system for this process. The Guide Block (Non-Trackable and Trackable) and the Trackable Awl are three additional tools now available for the ViewPoint. The Guide Blocks guide and track the trajectory of a biopsy needle during a procedure. The Trackable Awl is a standard awl that has been adapted to include infrared emitting diodes so that the tip of the awl can be tracked similar to the standard ViewPoint Y-probe.

4. **Safety and Effectiveness**

The use of the Sterrad 100 system adequately sterilizes the ViewPoint tools for intra-operative procedures and does not affect the accuracy or function of the tools. The Guide Blocks and the Trackable Awl described in this submission are equivalent to the tools described in the 510(k) submissions K963221 and K970604. This equivalence is demonstrated in the following table.

Substantial Equivalence Table

Parameter	ViewPoint - Sterrad	Predicate Devices
Tools	· Y-Probe with various tips · Cable · Head Tracker · Spine Tracker · Drill Guide (Non-Trackable and Trackable) · Guide Block (Non-Trackable and Trackable) · Trackable Awl	· Y-Probe with various tips · Cable · Head Tracker · Spine Tracker · Drill Guide (Non-Trackable and Trackable)
Material Considerations	Same.	Combination of metal and non-metal materials. IREDs on trackable tools are sensitive to heat.
Lumens	Same.	Trackable tools have a dead-end lumen in the LEMO Connector. The drill guides have a single-channel stainless steel lumen.
Use limits	Same.	None.
Accuracy (Y-probe)	Same.	Repeatability/Resolution: 1mm Distance measurement: ± 0.75 mm 3D Localization: ≤ 1.57 mm Fourth Fiducial Checkpoint: < 5.0 mm
Sterilization Technique	Sterrad	Ethylene Oxide
Intended Use	Same.	The ViewPoint is intended for use as a device that 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.

Parameter	ViewPoint - Sterrad	Predicate Devices
Indications for Use	Same.	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

JUL 8 1999

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

Re: K983764
Trade Name: ViewPoint Tools - Sterrad
Regulatory Class: II
Product Code: HAW
Dated: April 8, 1999
Received: April 9, 1999

Dear Dr. Keeler:

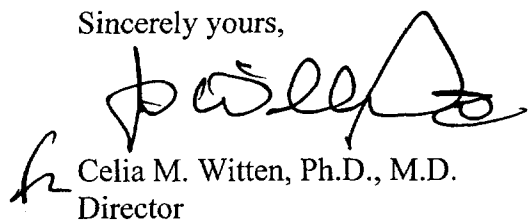
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K983764

Device Name: ViewPoint - Sterrad Sterilization

Indications for 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.

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.

(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 of General Restorative Devices
510(K) Number K983764

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)