

K98224A

SEP 23 1998

II SUMMARY AND CERTIFICATION

Summary of Safety and Effectiveness Mayfield® ACCISS™ Optical System

Pursuant to Section 513(I) of the Federal Food, Drug and Cosmetics Act.

1. General Information:

Classification Name: Stereotactic instrumentation

Common/Usual Name: Computer-based stereotactic surgical planning system

Proprietary Name: Mayfield® ACCISS™ Optical System

Applicant's Name and Address: Ken Miller, Regulatory Affairs Director
Ohio Medical Instrument Company, Inc. (OMI)
4900 Charlemar Drive
Cincinnati, Ohio 45227

2. Name of predicate device(s):

Mayfield® ACCISS™ Workstation (K955397)
Pelorus Arc Carrier (K874833)

3. Classification:

Neurosurgical stereotactic instruments and accessories are Class II (21CFR 882.4800).

4. Performance Standards:

No applicable performance standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description:

Intended Use: The Optical Tracking ACCISS™ System is intended to be used in an identical manner as the predicate device (Mayfield®/ACCISS™ Stereotactic Workstation). It is used for guidance and localization in open craniotomies and for surgeries, which are traditionally performed with a stereotactic apparatus, such as biopsies, thalamotomies and electrode implants. The system may also be used to review medical images in a neurosurgical context.

Device Description: The Optical Tracking ACCISS™ System is a computer-based system designed for use in the surgical theatre. It is a mobile design with the majority of the system components being self-contained in a cart. The camera assembly is separate from the cart components and it must be positioned above or beside the surgical site, preferably on a tripod or

II SUMMARY AND CERTIFICATION

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5. Intended Use and Device Description: - continued

dedicated camera stand. The camera assembly tracks the position and orientation of digitizing probes and other instruments. The computer is loaded with the patient's computed tomography (CT) or magnetic resonance image (MRI) data and these images are correlated to the patient by physically matching points, such as scanned fiducial markers, anatomical landmarks, or surface features. The host computer, interfaced with CT and /or MRI images, provides probe position and orientation. The probe manipulation by the surgeon appears on a monitor as it moves through space.

Three light-sensing cameras, the positions of which are known with respect to a predetermined coordinate system, detect the positions of at least two light-emitting diodes positioned on the probe. The cameras and probe transmit data to a computer and the position and orientation of the probe is determined relative to the coordinate system. The probe tip position is determined by correlating the tip position with the position of a scanned image of the object, both tip position and scanned image being defined relative to the predetermined coordinate system. A monitor connected to the computer indicates the location of the probe tip on the scanned image by displaying a representative location of the tip with respect to the model of the object.

The Optical Tracking ACCISS™ System consists of the following:

- A. **Workstation**
- B. **Software**
- C. **Probe Assembly**
- D. **Training Accessories**
 - (1) Plastic Skull
 - 50 CT/MRI Fiducial Markers
- E. **Optical Tracking Hardware Supported Modalities**

CT
MRI

Options:

Tektronix Phaser II SDX Color Printer
Overland Data 5612 9-Track Tape Drive

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6. Summary of Substantial Equivalence:

Indications: The Optical Tracking ACCISS™ System is intended to be used in an identical manner as the predicate device (Mayfield®/ACCISS™ Stereotactic Workstation, K955397) that is, stereotactic localization without the use of a conventional stereotactic frame as well as correlation of preoperative CT and/or MRI data with patients anatomy to assist in planning/performance of surgery.

Design: Mayfield®/ACCISS™ Workstation utilizes a mechanical articulated arm which acts as a 3-D digitizer; interfaced to computer graphics workstation which displays reformatted CT and MRI images in a variety of configurations.

The Optical System acts as a 3-D digitizer; interfaced to computer graphics workstation which displays reformatted CT and MRI images in a variety of configurations.

Materials: The materials used in the manufacture of the Mayfield®/ACCISS™ Optical System are the same as those used in the predicate device with the exception mentioned above under Design.

Manufacturing: The manufacturing processes used in the Optical System are the same as those used in the predicate device.

Specifications: The specifications of the Optical System are the same as those of the predicate device.

Conclusions: The indications, design, materials, manufacturing, and specifications of the Mayfield®/ACCISS™ Optical System do not raise any new unresolved issues relating to safety and effectiveness. Ohio Medical Instrument Company, Inc. thus considers the Mayfield®/ACCISS™ Optical System to be substantially equivalent to the predicate device.



SEP 23 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenneth B. Miller
Director, Regulatory Affairs/Quality Assurance
Ohio Medical Instrument Company, Inc.
4900 Charlemar Drive
Cincinnati, Ohio 45227

Re: K982244
Trade Name: Mayfield® ACCISS™ Optical System
Regulatory Class: II
Product Code: HAW
Dated: June 11, 1998
Received: June 25, 1998

Dear Mr. Miller:

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.

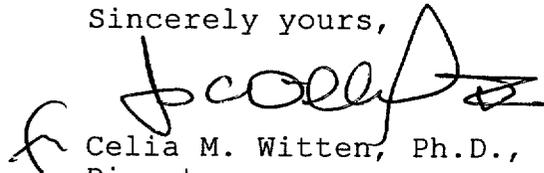
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Kenneth B. Miller

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) 594-4659. 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" (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): K982244

Device Name: Mayfield ACCISS Optical System

Indications For Use:

Intended Use: The Optical Tracking ACCISS™ System is intended to be used in an identical manner as the predicate device (Mayfield®/ACCISS™ Stereotactic Workstation). It is used for guidance and localization in open craniotomies and for surgeries, which are traditionally performed with a stereotactic apparatus, such as biopsies, thalamotomies and electrode implants. The system may also be used to review medical images in a neurosurgical context.

(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 K982244

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use