JUL 12 1999

II 510(k) SUMMARY AND CERTIFICATION

K991267

Summary of Safety and Effectiveness

Spine Applications
for the
MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems

Pursuant to Section 513(i) of the Federal Food, Drug and Cosmetics Act, as amended by the Safe Medical Devices Act [SMDA] of 1990.

Summary Preparation Date: April 9, 1999.

1. General Information:

Classification Name: Stereotactic Instrumentation

Common/Usual Name: Computer-Based Image-guided Stereotactic Surgery Planning System - Spine Applications

Proprietary Name: Spine Applications for the MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems.

Applicant's Name and Address:

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

2. Name of predicate device(s):

MAYFIELD®/ ACCISS™ Image-guided Stereotactic Workstation (K955397),
MAYFIELD®/Optical ACCISS™ Image-guided Stereotactic Workstation [OASYS™] (K982244),
BUDDE® Halo Retractor System [K830332]

3. Classification:

Neurosurgical stereotactic instruments and accessories are Class II (21CFR 882.4800 and 882.4560).

4. Performance Standards:

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

II 510(k) SUMMARY AND CERTIFICATION (continued)

5. Intended Use and Device Description:

Intended Use: The intended use of the MAYFIELD®/ ACCISS™ Image-guided Stereotactic Workstation [K955397] (hereafter referred to as the Arm System), and the MAYFIELD®/Optical ACCISS™ Image-guided Stereotactic Workstation [K982244] (hereafter referred to as the Optical System) is unchanged by Spine Applications for the MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems Module [4-12-A-1137] (hereafter referred to as Spine Applications). However, the Systems' indications for use have been expanded to include spinal surgery procedures.

The Arm and Optical Systems are intended for use as devices that use diagnostic images of the patient, acquired specifically to assist the surgeon with presurgical planning, to provide orientation and reference information during intra-operative procedures.

The MAYFIELD®/ ACCISS™ Image-guided Stereotactic Workstation and the MAYFIELD®/Optical ACCISS™ Image-guided Stereotactic Workstation (OASYS™) are indicated for use in guidance and localization in open craniotomies and in spinal surgeries. The ACCISS™ Systems are indicated for any medical condition in which the use of stereotactic surgery may be considered safe and effective, and where a reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model of the anatomy.

Device Description: Spine Applications is software that allows the user to select ["crop"] images of the portion of the spine under consideration from images of the entire spinal column. Also included is an accessory, the MAYFIELD®/ ACCISS™ Spine Ring™ Assembly (hereafter referred to as Spine Ring). The indications for use of the Arm and Optical Systems have been expanded to include use in spinal surgeries.

With Spine Applications, the Arm and Optical Systems can be used to identify spinal anatomical landmarks on the preoperative patient scans and also on the patient's spine to achieve registration with the imaged data set. After the correlation, the indication of the probe orientation appears on the monitor screen and moves through the CT or MRI data in correct relation to the probe as manipulated by the surgeon. This is the same process as that used in cranial surgery with the Systems.

With all image-guided surgery systems there must be a fixed positional relationship or link between the patient and the system. For cranial surgery, this link to the patient is achieved through the use of the Halo that is attached to the MAYFIELD® Skull Clamp A2000 [K932807] (hereafter referred to as the Skull Clamp). The Arm or the DRF is attached to the Halo, thereby achieving a firm and rigid relationship to the patient.

II 510(k) SUMMARY AND CERTIFICATION (continued)

5. Intended Use and Device Description: (continued)

For spinal procedures and use of Spine Applications, a similar "ring", the Spine Ring, may be used, if the surgeon elects. The Spine Ring is actually a segment of the Halo that can be connected to any standard spine retractor system. Attachment of the Spine Ring to the retractor that is attached to the patient achieves the same firm and rigid relationship to the patient as that of the Halo. The Spine Ring is sterilized via steam sterilization methods just as the Halo.

Spine Applications, in conjunction with the Arm and Optical Systems, is a computer-based system designed for use in the surgical theatre. The Arm System uses a position-sensing articulated Arm with a probe that acts as a localizing device. The Optical System uses a Sensor Assembly positioned above/beside the surgical site that tracks the position and orientation of digitizing probes and other instruments.

To use either System, 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 of anatomical landmarks. The System computer interfaces with CT or MR images and provides probe orientation/ probe-tip position. The indication of the probe orientation and probe-tip position appears on the monitor screen and moves through the CT or MRI data in correct relation to the probe as manipulated by the surgeon.

The Arm System and the Optical System, in conjunction with Spine Applications [the underlined items], consists of the following items:

A. Workstation
B. Software
- Includes MAYFIELD®/ ACCISS™ Spine Applications Module [4-12-A-1137]

C. Probe Assembly [articulated arm or optical tracking system]
- Includes MAYFIELD®/ ACCISS™ Spine Ring™ Assembly [4-12-C-1123]

D. Optical Tracking Accessories
E. Training Accessories
F. Supported Modalities
CT
MRI
G. Options:
Tektronix Phaser II SDX Color Printer
Overland Data 5612 9-Track Tape Drive

II 510(k) SUMMARY AND CERTIFICATION (continued)

6. Summary of Substantial Equivalence:

Spine Applications is substantially equivalent to the following devices:

- The MAYFIELD®/ ACCISS™ Image-guided Stereotactic Workstation [K955397],
- The MAYFIELD®/Optical ACCISS™ Image-guided Stereotactic Workstation (OASYS™) [K982244].
- The BUDDE® Halo Retractor System [K830332].

Indications:

- The Arm System and the Optical System, in conjunction with Spine Applications, are used in the identical manner as the predicate devices. Both Systems are used for localization as well as correlation of preoperative CT or MRI data with patient anatomy to assist in planning and/or performance of surgery. Spine Applications provides the surgeon with image-guided technology, using the identical algorithms currently used for cranial image-guidance, plus the ability to select or "crop" the images of the specific vertebral bodies involved.

- The Spine Ring is used in an identical manner as the predicate device to provide a rigid base for the Arm System or Optical System components and accessories.

Design:

- The Arm System, in conjunction with Spine Applications, utilizes a mechanical articulated Arm that acts as a 3-D digitizer, which interfaces to a computer graphics workstation that displays reformatted CT or MR images in a variety of configurations. The Optical System, in conjunction with Spine Applications, utilizes a 3-camera Sensor Assembly, a DRF with 3 LEDs, and a probe handle with 3 LEDs that acts as a 3-D digitizer. The Sensor Assembly interfaces to a computer graphics workstation that displays reformatted CT or MR images in a variety of configurations. Both Systems utilize the identical equipment and algorithms for image-guided cranial surgery planning and for image-guided spinal surgery planning. The spinal surgery planning algorithms of both Systems include the module for spinal vertebral body selection ["cropping"].

Materials:

- Materials used to manufacture Spine Applications and the Spine Ring are the same as those used for the predicate devices with the exceptions noted in Design, above.

Manufacturing:

- Manufacturing processes for Spine Applications and the Spine Ring are the same as those used for the predicate devices, with exceptions noted in Design, above.

Specifications:

- Specifications of Spine Applications and the Spine Ring are the same as those of the predicate devices, with the exceptions noted in Design, above.

II 510(k) SUMMARY AND CERTIFICATION (continued)

6. Summary of Substantial Equivalence: (continued)

Performance:

- The Arm System and the Optical System, both with Spine Applications, were used by surgeons under authority of the Institutional Review Boards for the hospitals involved. The Spine Applications performed to the surgeons' satisfaction with regard to preoperative planning and accuracy. The clinical data for Spine Applications compared favorably with the data for cranial surgery performed using the Systems.

7. Packaging:

The Arm and Optical Systems, Spine Applications, and the Spine Ring are supplied in industry standard medical-grade packaging suitable for electronic equipment and surgical instruments. The shippers and cartons are of suitable design to ensure product identification and protection from damage during shipping and storage.

8. Sterilization:

The Arm and Optical Systems, Spine Applications, and the Spine Ring are supplied **NON-STERILE**. These non-sterile devices are packaged in "clean" condition, and must be removed from their shipping and packing materials, then appropriately cleaned before use as described in the instruction manuals.

A sterilization process, following AAMI TIR No. 12-1994, has been validated for the Spine Ring and the Halo. The validated sterilization cycle for the Halo and the Spine Ring is:

- **Steam sterilization at 132 degrees C, under high vacuum [2.0 psia] for 3 minutes [STS Test No.: 98-3359, STS Study No. GMP-1998-0082, on file at OMI].**

The Instruction Manuals for Spine Applications, the Optical System, and the Arm System provide instructions on sterile use and reprocessing of components that require sterilization by the user.

9. Conclusion:

The Intended Use, Indications for Use, Design, Materials, Manufacturing, Specifications, Performance, Packaging and Sterilization of Spine Applications and the Spine Ring do not raise any new unresolved issues relating to safety and effectiveness. Ohio Medical Instrument Company, Inc. therefore considers Spine Applications and the Spine Ring as substantially equivalent to the predicate devices.

II 510(k) SUMMARY AND CERTIFICATION (continued)

10. Comparison Table:

FEATURE	MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems [K955397, K982244]	Spine Applications for the MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems
Intended Use	The Arm System and the Optical System are intended for use as devices that, by the use of diagnostic images of the patient, acquired specifically to assist the surgeon with presurgical planning, provide orientation and reference information during intra-operative procedures.	• Same.
Indications for Use	The Arm System and the Optical System are indicated for: • Guidance and localization in open craniotomies, and for surgeries that are traditionally performed with a stereotactic apparatus, such as biopsies, thalamotomies, and electrode implants. The Systems may also be used to review medical images in a neurosurgical context.	The Arm System and Optical System, with Spine Applications, are indicated for: • Use in guidance and localization in open craniotomies and in spinal surgeries. The ACCISS™ Systems are indicated for any medical condition in which the use of stereotactic surgery may be considered safe and effective, and where a reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model of the anatomy.
Design	• Arm or Optical tracking for 3-D digitizing. • Interfaces to computer graphics workstation. • Displays reformatted CT or MR images in variety of configurations. • Algorithms for image-guided surgery planning. • Software to show body part undergoing surgery - head.	• Same. • Same. • Same. • Same. • Same. • Software to show body part undergoing surgery - spine.

II 510(k) SUMMARY AND CERTIFICATION (continued)

10. Comparison Table: (continued)

FEATURE	MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems [K955397, K982244]	Spine Applications for the MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems
Type of Detector	• Optically encoded signals from joints of articulated arm. • A 3-camera Sensor Assembly detects infrared signals emitted from LEDs on hand-held probe handle. The Sensor Assembly is mounted on a dedicated, mobile stand.	• Same. • Same.
Registration Technique	• Scanned Fiducials • Anatomical Fiducials	• Same. • Same.
Operating Software	• Structure: MS-DOS, with two major functions: Image Importation, and Surgical Applications [navigation]. Uses a Graphical User Interface to facilitate interaction with user. • Image Manipulation: Unreformatted, reformatted, 3-D surface rendering.	• Same. Modified Graphical User Interface with similar functionality. • Same.
Materials	• Aluminum 6061 [anodized] for tracking probe [K853627 for use of anodized aluminum]. • Stainless steel ASTM F899, passivated QQ-P-35 Type 2 for sterile probe-tips.	• Same • Same
Accessories	• BUDDE® Halo Retractor System [K830332]	• Same. • MAYFIELD®/ ACCISS™ Spine Ring™ Assembly [4-12-C-1123]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

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

Re: K991267
Trade Name: MAYFIELD® ACCISS™ Operating Arm and Optical ACCISS™ Systems
Regulatory Class: II
Product Code: HAW
Dated: April 9, 1999
Received: April 13, 1999

Dear Mr. Miller:

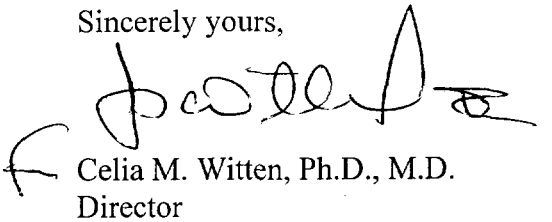
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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) 594-4659. 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,



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): K991267

Device Name: Spine Applications for the MAYFIELD®/ACCISS™ Operating Arm and Optical ACCISS™ Systems

Indications For Use:

The MAYFIELD®/ ACCISS™ Image-guided Stereotactic Workstation and the MAYFIELD®/Optical ACCISS™ Image-guided Stereotactic Workstation (OASYS™), are indicated for use in guidance and localization in open craniotomies and in spinal surgeries. The ACCISS™ Systems are indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model of the anatomy.

(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 K991267

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format - 1 - 2 - 96)