OHIO
MEDICAL
INSTRUMENT
COMPANY INC. CINCINNATI, OHIO 45227

NOV - 2 1999

K992f43

II 510(k) SUMMARY

Summary of Safety and Effectiveness

MAYFIELD®/ ACCISS™ System with Windows NT® for Cranial Surgery and MAYFIELD® Optical ACCISS™ System with Windows NT® for Cranial Surgery and with the Wireless Probe/Dynamic Reference Frame

This Summary is submitted pursuant to Section 513(i) of the Federal Food, Drug and Cosmetics Act, as amended by the Safe Medical Devices Act [SMDA] of 1990, and in accordance with the requirements of 21 C.F.R. § 807.92.

1. This Summary was prepared on August 20, 1999.
   The Submitter's Name and Address & the name of the Contact Person are:
   Ohio Medical Instrument Company, Inc.
   4900 Charlemar Drive
   Cincinnati, Ohio 45227 U.S.A.
   Phone: (513) 561-2241 Fax: (513) 561-0195
   Kenneth B. Miller, Director, Regulatory Affairs and Quality Assurance

2 This Premarket Notification describes modifications to the MAYFIELD®/ ACCISS™ System [hereafter Arm System] and to the MAYFIELD®/ Optical ACCISS™ System [hereafter Optical System]. The common name of these Systems is Computer-Based Image-Guided Stereotactic Surgery Planning Systems, and the classification name is Stereotactic Instrumentation.

3. The predicate devices are the MAYFIELD®/ ACCISS™ Image-Guided Stereotactic Workstation (K955397) and the MAYFIELD®/ Optical ACCISS™ Image-Guided Stereotactic Workstation [OASYS™] (K982244).

4. The modifications apply to cranial surgery and involve: a) conversion of the operating system software for both Systems to Windows NT [hereafter "Windows"] from DOS, and b) addition of a battery-powered Wireless Probe and battery-powered Wireless Dynamic Reference Frame [hereafter Wireless Probe/DRF] for use with the Optical System.

5. "Windows" is operating system software that, in conjunction with the Arm and Optical Systems, allows the user to select and simultaneously display and/or keep on the screen a number of images of interest, "zoom" images to larger sizes and move images to different locations on the monitor screen. "Windows" replaces and is substantially equivalent to the DOS operating system software used by the predicate Systems. Changes to the overall design of the screens and to the way the Systems are used have been minimized to make the transition easy for the user.

Windows NT is a registered trademark of Microsoft Corp.

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II 510(k) SUMMARY (continued)

6. The Wireless Probe/DRF each carries a sterile battery for their power. When coupled with the Optical System, the wireless models function in the same way as the wired versions by allowing preoperative and operative planning surgical procedures using CT or MR images.

7. The addition of "Windows" and the Wireless Probe/DRF has not changed the Intended Use of the Arm System and the Optical System. 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. There are no operational differences between "Windows" and DOS or between the Wireless Probe/DRF and the wired Probe/DRF. All phases of preoperative and operative planning for cranial surgery remain the same.

8. "Windows" is operating system software that replaces the predicate DOS operating system software. It does not introduce any technological changes to the Systems other than the ability to display and/or keep a number of images simultaneously on the monitor screen, "zoom" the images to larger sizes and move the images to different locations on the monitor screen. With the exception of the power source, the technological characteristics of the Wireless Probe/DRF are the same as or similar to those of the predicate wired devices where LED-based systems and infrared signals are used to provide tracking information as an aid to surgery.

9. Tests simulating cranial surgery planning were performed using the Arm System with "Windows" and the Optical System with "Windows" and with the Wireless Probe/DRF. The results were compared to the results of the same tests performed with the DOS-based Systems and with the wired Probe and DRF. This comparison demonstrated that the functions of the Arm and Optical Systems were unchanged.

10. Based upon the above points, OMI has concluded that for cranial surgery, the Arm System with "Windows" and the Optical System with "Windows" and with the Wireless Probe/DRF do not raise any new unresolved issues relating to safety and effectiveness. Ohio Medical Instrument Company, Inc. therefore considers the Arm System with "Windows" and the Optical System with "Windows" and with the Wireless Probe/DRF, to be substantially equivalent to the predicate Systems.

K992093

II 510(k) SUMMARY (continued)

Summary of Substantial Equivalence - Comparison Table

FEATURE	MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems [K955397, K982244]	MAYFIELD®/ ACCISS™ System with "Windows" for Cranial Surgery and MAYFIELD® Optical ACCISS™ System with "Windows" for Cranial Surgery and with the Wireless Probe/DRF
Intended Use	The Systems 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.	The Systems are intended for use as: • Same.
Indications for Use	The Systems are indicated for use in: • 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 neurological context.	The Systems are indicated for use in: • Same.
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-with Wireless Probe/DRF for Optical System. • Same • Same-with ability to simultaneously display and/or keep multiple images on screen, "zoom" images to larger sizes, and move images on screen • Same • 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

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II 510(k) SUMMARY (continued)

Summary of Substantial Equivalence - Comparison Table

FEATURE	MAYFIELD®/ ACCISS™ Operating Arm and Optical ACCISS™ Systems [K955397, K982244]	MAYFIELD®/ ACCISS™ System with "Windows" for Cranial Surgery and MAYFIELD® Optical ACCISS™ System with "Windows" for Cranial Surgery and with the Wireless Probe/DRF
Sterilization	• Systems shipped non-sterile. User cleans and sterilizes prior to use. • Steam sterilization method validated for metal components and accessories.	• Same-except for the packaged sterile batteries for the Wireless Probe/DRF that are shipped separately. • Same-includes wireless Probe/DRF.
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. • The Probe handle and DRF each have LEDs that are electrically powered by a wire from workstation.	• Same • Same-with Transmitter for Wireless Probe/DRF mounted with Sensor Assembly. • Same-except the Wireless Probe/DRF each carries a sterile battery for power.
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 users. • Image Manipulation: Unreformatted, reformatted, 3-D surface rendering.	• Structure: "Windows", with same two major functions. • Uses Modified Graphical User Interface with similar functionality. • Same-with multiple images displayed, "zoom" of image, able to move images on screen.
Accessories	• BUDDE® Halo Retractor System [K830332]	• Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 1999

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

Re: K992843
Trade Name: MAYFIELD®/ACCISS™ Operating Arm System with Windows NT® for Cranial Surgery and MAYFIELD®/Optical ACCISS™ System (OASYS™) with Windows NT® for Cranial Surgery and with the Wireless Probe/Dynamic Reference Frame
Regulatory Class: II
Product Code: HAW
Dated: August 20, 1999
Received: August 24, 1999

Dear Mr. Miller:

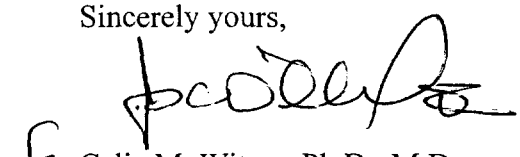
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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): K992843

Device Name: MAYFIELD®/ACCISS™ Operating Arm System with Windows NT® for Cranial Surgery and MAYFIELD® Optical ACCISS™ System with Windows NT® for Cranial Surgery and with Wireless Probe/Dynamic Reference Frame

Indications for Use:

The MAYFIELD®/ ACCISS™ Operating Arm System with Windows NT® for Cranial Surgery and the MAYFIELD®/Optical ACCISS™ System (OASYS™) with Windows NT® for Cranial Surgery and with Wireless Probe/Dynamic Reference Frame are indicated for use in 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.

(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 K992843
510(k) Number

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

(Optional Format - 1 - 2 - 96)