JUN 1 - 2005

K041897

II. SUMMARY AND CERTIFICATION

Summary of Safety and Effectiveness Mayfield® ACCISS™ II Image Guided Surgery System

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

1. General Information:

Classification Name: Stereotactic instrumentation

Common/Usual Name: Image Guided Surgery System

Proprietary Name: Mayfield® ACCISS™ II Image Guided Surgery System

Applicant's Name and Address:

Teck W. Awa
Schaerer Mayfield USA, Inc.
4900 Charlemar Drive
Cincinnati, Ohio 45227

2. Name of predicate device(s):

Mayfield® ACCISS™ Operating Arm System and Mayfield® Optical ACCISS™ System (K013428)
Nicolet Biomedical Electromagnetic Navigational System (K013419)

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: Mayfield® ACCISS™ II Image Guided Surgery System is indicated for open and percutaneous procedures for any medical condition where reference to a rigid anatomical structure such as the skull, a long bone, or vertebra can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy and the use of stereotactic surgery may be considered appropriate. Representative uses would be for cranial, spinal and ENT procedures.

II. SUMMARY AND CERTIFICATION

Summary of Safety and Effectiveness Mayfield® ACCISS™ II Image Guided Surgery System

5. Intended Use and Device Description: - continued

Device Description:
The Mayfield® ACCISS™ II Image Guided Surgery System comprises a cart, power supplies (including an isolating transformer), a PC workstation running the software and tracking devices.

The Mayfield® ACCISS™ II Image Guided Surgery System supports two different tracking devices; Optical and Electromagnetic Tracking devices. The tracking devices track the position and orientation of surgical probes and other instruments. The computer is loaded with the patient's image data and these images are correlated to the patient by physically matching points, such as scanned fiducial markers and anatomical landmarks.

In the optical tracking method, the configuration of infrared light points is detected by two cameras in two different perspectives in order to calculate the spatial position of the point configuration. With this method, the cameras must constantly maintain a line of sight with the instruments. This inconvenience can be eliminated by the use of measuring ectromagnetic fields technique. The electromagnetic transmitter can be placed underneath the operating table and covered.

An image guidance procedure can be performed based on pre-operative (CT/MRI) or intra-operative acquired diagnostic images, like intra-operative MRI, CT or Fluoroscopy. The Mayfield® ACCISS™ II Image Guided Surgery System must first establish a correlation between the diagnostic images and the "real world" of the operating room so that the position of special surgical instruments, such as a pointer or surgical tool, can be portrayed within the scanned images. This process is called image data registration. Clearly and easily identified markers in both the "real world" and the "image world" are used. These markers can be anatomical as well as artificial landmarks, which will be attached to the patient before image acquisition. The artificial markers (fiducials) have a defined shape and contrast medium appropriate for the imaging procedures. The Mayfield® ACCISS™ II Image Guided Surgery System uses a two-component marker system. The markers with contrast medium are attached to a self-adhesive pad before they are affixed to the prepared skin of the patient. These markers will be removed after the scanning procedure, but the adhesive pads must remain on the patient until surgery. The artificial landmarks will be automatically identified and located within the image data by the Mayfield® ACCISS™ II Image Guided Surgery System during the data preparation.

The images from the scanner are archived in a specific data format and stored in a specific data medium, or transmitted directly to the Mayfield® ACCISS™ II Image Guided Surgery System over the network. The system supports the DICOM data format and the DICOM data transfer. Other data formats and transfer protocols are supported by customer specifications.

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Summary of Safety and Effectiveness Mayfield® ACCISS™ II Image Guided Surgery System

5. Intended Use and Device Description: - continued

After successful review the transferred data for quality and consistency, the images slices are then combined in a three-dimensional volume and viewed on the monitor screen as axial, sagittal and coronal orthogonal images. The user can now manually check for image quality, image orientation and patient identification. Artifacts can be sliced off (at least at the screen border) without changing the image content. The brain, lesions or special access paths and landmarks can be segmented and displayed as three-dimensional objects which can be useful during planning and navigation process.

In the operating room, measuring aids (i.e., registration markers) will be attached to the adhesive pads. After selection of the tracking system (optical/electromagnetic), the markers positions (fiducials and anatomical landmarks) are repeatedly measured by pressing the function button on the pointer. This measurement routine creates a correlation between the data and the "real world. During this procedure, the number of measured points and the number of clusters found are displayed. A cluster describes the position of one unique marker point. The Mayfield® ACCISS™ II Image Guided Surgery System assigns a cluster to a correct image point automatically. At least four cluster pairs are required to establish an image registration. The system shows the fiducial registration error (FRE) and presents a prediction of the target registration error (TRE) to provide the surgeon with a rough quality gauge of the image accuracy. However, even a good error prediction cannot replace surgeon expertise. That's why the surgeon is responsible to verify the given information by proofing the markers position as well as well-defined anatomical landmarks close to the region of interest.

Once the registration is completed, the pointer's position to the patient's head is displayed in the scanned images. The marker pads can be removed once the registration quality satisfies the surgical needs and requirements. The surgical area can be cleaned and draped.

The pointer used for image registration is replaced with a sterile instrument and cranial navigation can begin. The system automatically recognizes this new instrument. In case of using surgical tools with an intra-operatively mounted position sensor an instrument calibration has to be performed first.

The surgeon can define a reachable area near the operating field, in which he or she is able to control the Mayfield® ACCISS™ II Image Guided Surgery System via the pointer device. If the instrument reaches this defined area, the system switches from navigation mode to control mode. Through spatial movement within the defined area, the surgeon can control all essential guidance functions by pressing the function key on the instrument.

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Summary of Safety and Effectiveness Mayfield® ACCISS™ II Image Guided Surgery System

6. Summary of Substantial Equivalence:

Indications: Mayfield® ACCISS™ II Image Guided Surgery System is intended to be used in an identical manner as the predicate devices that is used to interactively provide image guidance during cranial, ENT and spinal procedures.

Design: The Mayfield® ACCISS™ II Image Guided Surgery System is designed to utilize an optical tracking device that is similar to those used in the predicate device and an electromagnetic tracking device that is similar to those used in the predicate device as a 3-D digitizer to interface with the computer workstation to provide image guided surgery using a CT or MR based model or fluoroscopy images of the anatomy.

Materials: The materials used in the manufacture of the Mayfield® ACCISS™ II Image Guided Surgery System are similar to those used in the predicate devices.

Manufacturing: The manufacturing processes used in the Mayfield® ACCISS™ II Image Guided Surgery System are similar to those used in the predicate devices.

Specifications: The specifications of the Mayfield® ACCISS™ II Image Guided Surgery System are similar to those of the predicate devices.

Conclusions: The indications, design, materials, manufacturing, and specifications of the Mayfield® ACCISS™ II Image Guided Surgery System do not raise any new unresolved issues relating to safety and effectiveness. Schaerer Mayfield USA, Inc. thus considers the Mayfield® ACCISS™ II Image Guided Surgery System to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2005

Mr. Teck Awa
Product Manager
Schaerer Mayfield USA Incorporated
4900 Charlemar Drive
Cincinnati, Ohio 45227

Re: K041897
Trade/Device Name: Mayfield® Acciss™ II Image Guided Surgery System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 25, 2005
Received: April 26, 2005

Dear Mr. Awa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041897

Device Name: **MAYFIELD® ACCISS™ II IMAGE GUIDED SURGERY SYSTEM**

Indications For Use:

MAYFIELD® ACCISS™ II IMAGE GUIDED SURGERY SYSTEM is indicated for open and percutaneous procedures for any medical condition where reference to a rigid anatomical structure such as the skull, a long bone, or vertebra can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy and the use of stereotactic surgery may be considered appropriate. Representative uses would be for cranial, spinal and ENT procedures.

Prescription Use ___x____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative and Neurological Devices

(Division Sign-Off) K041897