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SECTION 5: 510(k) SUMMARY

510(k) Owner/Submitter:
Dinkler Surgical Devices, Inc.
174 Lookout Drive
Dayton, Ohio 45419
Phone: (513) 310-0017 Fax: (937) 395-0787

Contact Name: Charles E. Dinkler II
Contact Title: President

Summary Preparation Date: October 25, 2007

Trade Name: Limited Artifact Skull Pin
Common/Usual Name: Skull Pins
Classification Name: Holder, Head, Neurosurgical (Skull Clamp §882.4460)

Identification of legally marketed device to which equivalence is claimed (Predicate Device): Dinkler Surgical Devices believes based on the information provided that the Limited Artifact Skull Pin is substantially equivalent to the Mayfield Disposable Skull Pin 4-0-A-1072 (K923789).

Device Description:
The Limited Artifact Skull Pins consists of an injection molded PEEK polymer base, a machined titanium pin tip, and an O-ring. These components are assembled to each other to represent the finished skull pin. The pins are packaged three (3) pins per pouch, twelve (12) pouches per carton and radiation sterilized.

Intended Use:
Limited Artifact Skull Pins are used with a head holder device that is placed on the patients' skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired.

Target Population:
The target population for the limited artifact skull pins is that part of the population that requires the use of a head holder to fixate their head and neck in a particular position during surgical procedures and during intra-operative use within a MR environment rated up to and including a 1.5 Tesla magnetic field.

Indication For Use Statement Differences
The indications for the Limited Artifact Skull Pins are identical to the indications for the predicate device with the following exception: The limited artifact skull pins are also indicated

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for use during magnetic resonance Imaging (MRI) procedures within a MR environment rated up to and including a 1.5 Tesla magnetic field. The difference in materials used in the Limited Artifact Skull Pins does not compromise its safety and effectiveness, but enhances the ability for it to perform in such a magnetic environment.

Summary of Technological Characteristics

FEATURE	Limited Artifact Skull Pin	Mayfield Disposable Skull Pin
Intended Uses	Used with head holders to clamp the patient's skull and hold the head and neck in position during surgical procedures.	Used with head holders to clamp the patient's skull and hold the head and neck in position during surgical procedures.
Indications for Use	Indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and during intra-operative use within a MR environment rated up to and including a 1.5 Tesla magnetic field.	Indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary.
Materials	The pin tip is titanium 6Al4V and the polymer pin base is PEEK with 10% carbon filler.	The pin point is stainless steel and the polymer base is ABS plastic.
Manufacturing	The pin tip is machined to the dimensions listed on the pin tip drawing. The pin base is injection molded to the dimensions listed on the pin base drawing.	The pin point is machined. The pin base is injection molded.
Preparation for Surgery	None, the pins are supplied sterile in a 3-pack pouch ready for use.	None, the pins are supplied sterile in a 3-pack pouch ready for use.
Method of Use	Typically, three (3) pins are installed in receptacles of a head holder.	Typically, three (3) pins are installed in receptacles of a head holder.
Performance	Combined Load Testing - No failures Maximum Vertical Loading in a Skull Clamp - Pin failure MRI Testing - MR Conditional	Combined Load Testing - No failures Maximum Vertical Loading in a Skull Clamp - Pin slip None
K-Number	K073163	K923789
Manufacturer	Dinkler Surgical Devices, Inc.	Integra Lifesciences

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Design:
Both the Limited Artifact Skull Pins and the Mayfield Disposable Skull Pins are used in the same head holders for surgical approaches that require rigid skeletal fixation. Both products may be used to treat the same medical or surgical conditions of the brain and cervical spine. Both products have essentially the same cautions and contraindications for use.

Materials:
Both the Limited Artifact Skull Pins and the predicate device utilize a similar molded base made of different plastic materials. The limited artifact skull pin is molded from a PEEK polymer with a 10% carbon additive and the predicate device is molded from ABS.
The limited artifact pin tip is made from titanium alloy, whereas the predicate device pin point is made of 17-4PH stainless steel.

Packaging:
The Limited Artifact Skull Pins are supplied in the same packaging that is used by the predicate device - industry standard medical grade packaging [sealed TYVEK/flexible film pouches] suitable for sterile surgical devices. The Box Carton is of suitable design and materials to ensure product sterility, identification and protection from damage during shipping and storage and is nearly identical or the same as that used by the predicate device.

Sterilization:
The Limited Artifact Skull Pins are supplied to the surgeon sterile, as are the predicate devices. These devices are cleaned by Dinkler Surgical Devices using a process to remove manufacturing residue, assembled, packaged and sealed, and then shipped to a contract sterilizer where they are radiation sterilized using a validated process, ANSI/AAMI/ISO 11137. The Sterility Assurance Level (SAL) of the validated sterilization cycle is 10^{-6} (SAL 10^{-6}).

Non-Clinical Tests
1. Combined Axial and Shear Loading in a Skull Clamp
Mechanical testing of the pins was performed by simulating the loads on them as they are applied during surgery. Pins were placed in a skull clamp and a load was applied to fixate the test block "head" in the clamp. Another load was applied to the test block to simulate the patient's head weight and an external load being pressed down on the head during surgery.
2. Duration Loading in a Skull Clamp
Pins were placed in a skull clamp and a load was applied to fixate the test block "head" in the clamp. Another load was applied to the test block to simulate the patient's head weight during surgery. The clamp was left in this manner for a period of time.
3. Axial and Shear Cycle Loading in a Skull Clamp
Pins were placed in a skull clamp and a load was applied to fixate the test block "head" in the clamp. Another load was applied to the test block to simulate the patient's head weight. Another load was applied to the test block to simulate the surgeon pressing down on the head of the patient during surgery. This load was applied repeatedly for a given number of cycles.

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4. Combined Axial and Maximum Shear Loading in a Skull Clamp
Pins were placed in a skull clamp and a load was applied to fixate the test block "head" in the clamp. A maximum load was applied to the test block to simulate the patient's head weight and an external load being pressed down on the head during surgery.
5. MRI Testing
Testing was performed on the Limited Artifact Skull Pins to support the claim that it is MR Conditional and determine the degree of artifact it may produce.

Conclusions of Non-Clinical Tests
The mechanical testing that was performed shows that the Limited Artifact Skull Pins performance is substantially equivalent to the predicate device while subjected to loading similar to an operating room procedure.

The MRI testing revealed significantly less artifact than what can be offered with magnetic stainless steel [predicate device] pins. The Limited Artifact Skull Pin is superior to the predicate device in this regard.

The pin tips of both the Limited Artifact Skull Pins and the predicate device excelled no differently in all of the tests performed. The tips had sufficient durability during penetration exercises of the "head" fixture. The Limited Artifact Skull Pin is substantially equivalent to the predicate device in this regard.

Conclusion:
The Limited Artifact Skull Pin tips are machined and the plastic bases are molded, in the same manner as the predicate device [4-0-A-1072 pins]. The Limited Artifact Skull Pin components are cleaned, assembled, packaged, and sterilized in a similar manner as the predicate device pins.

The bench testing that was performed shows the device to be equivalent to the predicate device during testing of the device as used in a typical operating room procedure. In addition, testing also shows the Limited Artifact Skull Pin to have exceptional properties in the presence of a magnetic field.

Based on the information provided above, Dinkler Surgical Devices, Inc. considers the Limited Artifact Skull Pin, model number 0107 Adult, to be substantially equivalent to the predicate device, the Mayfield Disposable Skull Pins 4-0-A-1072.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Dinkler Surgical Devices, Inc.
% Mr. Charles E. Dinkler, II
President
174 Lookout Drive
Dayton, Ohio 45419

Re: K073163
Trade/Device Name: Limited Artifact Skull Pin
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: February 16, 2008
Received: February 20, 2008

Dear Mr. Dinkler:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K073163

Device Name: Limited Artifact Skull Pin

Indications For Use:

The Limited Artifact Skull Pins are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is required and during intra-operative use within a MR environment rated up to and including a 1.5 Tesla magnetic field.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Section 4.1

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SECTION 4: INDICATIONS FOR USE (continued)

Further Explanation:

The Limited Artifact Skull Pins are used in open and percutaneous craniotomies such as biopsies, thalamotomies and electrode implants; and in spinal surgeries when rigid skeletal fixation is necessary. The pins are also indicated for use during intra-operative use within a MR environment rated up to and including a 1.5 Tesla magnetic field.

The target population for the limited artifact skull pins is that part of the population that requires the use of a head holder to fixate their head and neck in a particular position during surgical procedures.