K090695

SECTION 5: 510(k) SUMMARY

510(k) Owner/Submitter:
Dinkler Surgical Devices, Inc.
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Dayton, Ohio 45419
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Contact Name: Charles E. Dinkler II
Contact Title: President

APR 2 3 2009

Summary Preparation Date: February 13, 2009

Trade Name: Dinkler Surgical Skull Clamp
Common/Usual Name: Skull Clamp
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 Skull Clamp is substantially equivalent to the Mayfield A2000 Skull Clamp (K932807) and the Sugita Multi-Purpose Head Frame (K955012 non-Radiolucent Model).

Device Description:
The Dinkler Surgical Skull Clamp is a device used for rigid fixation of the skull.

The design of the Skull Clamp allows the surgeon more freedom in positioning the skull pins. Avoidance of critical areas of the skull is made possible by a swiveling rocker arc which rotates 360°.

The main body of the clamp is made from aluminum. The rocker arc assembly, which houses an additional skull pin, is made from stainless steel. A torque screw device on the main body of the clamp is used to apply load to the skull mainly for support and an additional torque screw, on the arc, provides load to resist head rotation. To accommodate the different sizes of patient heads, the skull clamp can be slid opened or closed and then locked.

Indications for Use:

The Dinkler Surgical Skull Clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

K090695

Summary of Technological Characteristics

FEATURE	Dinkler Surgical Skull Clamp	Mayfield A2000 Skull Clamp	Sugita Multi-Purpose Head Frame
Intended Use	Is placed on the patient's skull to hold their head and neck securely in a particular position	Is placed on the patient's skull to hold their head and neck securely in a particular position	Clamping of a patient's head and neck in a particular position during surgical procedures.
Indications for Use	Indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	Indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary.	Clamping of a patient's head and neck in a particular position during surgical procedures.
Materials	Aluminum and stainless steel.	Aluminum and stainless steel.	Aluminum and stainless steel.
Manufacturing	Components are machined by conventional methods using manual or CNC machinery.	Components are machined by conventional methods using manual or CNC machinery.	Components are machined by conventional methods using manual or CNC machinery.
Preparation for Surgery	Thoroughly clean by scrubbing with a brush and neutral pH detergent.	Thoroughly clean by scrubbing with a brush and neutral pH detergent.	Wash with running water and neutral detergents.
Method of Use	Install (3) skull pins in clamp, maneuver into position, seat opposing skull pins to desired reading, adjust and seat rocker arc pin to desired reading, readjust opposing pin readings if necessary.	Install (3) skull pins in clamp, maneuver into position, adjust rocker arm, seat skull pins to desired reading and then back off one quarter turn.	Maneuver head into position, seat opposing pins to desired reading, seat angled pins to desired reading, and readjust opposing pin reading if necessary.
Performance	Load Testing - Vertical Loading in a Skull Clamp - Maximum horizontal clamp loading	Load Testing - Vertical Loading in a Skull Clamp - Maximum horizontal clamp loading	Load Testing - Vertical Loading in a Skull Clamp - Maximum horizontal clamp loading
K-Number	To Be Assigned	K932807	K955012 Non-Radiolucent Model
Manufacturer	Dinkler Surgical Devices, Inc.	Integra Lifesciences	Mizuho America Inc.

Design:
Both the Dinkler Surgical Skull Clamp and A2000 predicate device are adjustable to accept various head sizes of the patient. Each device has a rocker on one end similar to the A2000. In addition, the Dinkler Surgical Skull Clamp can be converted to having a rocker arc on both ends similar to having 4-point fixation like the Sugita Multi-Purpose Head Frame.

The Dinkler Surgical Skull Clamp rocker arc retains a single skull pin, whereas the predicate skull clamp retains 2 skull pins. Both have the means for skull pin force calibration by advancing a torque screw.

Both devices have a release mechanism that allows for quick removal of the clamp.

K090695

The Sugita Multi-Purpose Head Frame is a fixed clamp with no adjustability for head sizes. It has no rocker pin features, but uses a four (4) point system to clamp a patient's head during surgical procedures.

The Dinkler Surgical Skull Clamp and both predicate devices are placed on the patient's skull to hold their head and neck securely during neurosurgical and cervical spine procedures. Various clamp positions are obtainable by using a table adapter, which is fixed to the table and supports the clamp. The table adapter is provided separately and is not the subject of this 510(k).

Materials:
All three devices do not directly contact the patient and they utilize similar materials- aluminum and stainless steel.

Sterilization:
All three skull clamps are supplied to the customer in a clean, non-sterile condition. The skull clamp does not come into direct contact with the patient. Before each use the clamp and its components should be wiped with a disinfectant per hospital protocol.

Non-Clinical Tests
1) Vertical Loading in a Skull Clamp
Mechanical testing of the clamp was performed by simulating the loads on it as they are applied during surgery. A load was applied to fixate a 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) Maximum Horizontal Loading in a Skull Clamp
A load was applied to the clamp in order to spread the "C" arms apart.

Conclusions of Non-Clinical Tests
The results of the 2 tests show the Dinkler Surgical Skull Clamp performance to be more than adequate and very acceptable in fixating the skull.

Conclusion:
The Dinkler Skull Clamp and the two (2) predicate devices have the same indications for use. They are manufactured similarly from like materials and use the same method of cleaning before use. The method of use is slightly different among the three (3) skull clamps.

The bench testing that was performed shows that the clamp can support the loads that are imposed on it. Historical use of the predicate devices shows that they too can support the loads that are necessary.

Based on the information provided above, Dinkler Surgical Devices, Inc. considers the Skull Clamp, CAT. No. 0308, 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

Dinkler Surgical Devices, Inc.
c/o Charles E. Dinkler II
President
174 Lookout Drive
Dayton OH 45410

APR 23 2009

Re: K090695
Trade/Device Name: Dinkler Surgical Clamp
Regulation Number: 21 CFR 882.4460
Regulation Name: Holder, head, neurosurgical (skull clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: March 12, 2009
Received: March 16, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090695

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K090695

Device Name: Dinkler Surgical Skull Clamp

Indications For Use:

The Dinkler Surgical Skull Clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

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 Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090695