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AUG 29 2008

ABBOTT SPINE, INC.
SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Abbott Spine Inc.
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	Maritza Elias Senior Regulatory Affairs Specialist Telephone: 512.533.1908 Fax: 512.918.2784
DATE:	August 28, 2008
TRADE NAME:	Universal Clamp® Stainless Steel System
PRODUCT CODE:	JDQ
CLASSIFICATION NAME:	Bone Fixation Cerclage
CLASSIFICATION REFERENCE:	21 CFR § 888.3010
PREDICATE DEVICE:	Abbott Spine Universal Clamp System (Ti)
DEVICE DESCRIPTION:	The Universal Clamp Stainless Steel System is a temporary orthopedic implant intended to provide stabilization during the development of solid bony fusion and aid in the repair of bone fractures. The device system is designed to be incorporated into constructs and used in conjunction with other medical implants made of stainless steel whenever "wiring" may help secure the attachment of other implants.
INDICATIONS:	The Universal Clamp Stainless Steel System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone factures. The indications for use include, but are not limited to, the following applications: 1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques; 2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction

of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;

3. Spinal degenerative surgery, as an adjunct to spinal fusions;

The Universal Clamp Stainless Steel System may also be used in conjunction with other medical implants made of stainless steel whenever "wiring" may help secure the attachment of other implants.

SUBSTANTIAL EQUIVALENCE:

Engineering evaluations and bench testing were conducted to assess the physical and mechanical properties of the subject device. These results demonstrate that the performance of the Abbott Spine Universal Clamp® Stainless Steel System is substantially equivalent to the predicate titanium alloy version cleared in premarket notification K060009.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2008

Abbott Spine, Inc
% Ms. Maritza Elias
Senior Regulatory Affairs Specialist
5301 Riata Park Court, Building F
Austin, Texas 78727

Re: K081622
Trade/Device Name: Abbott Spine Universal Clamp® Stainless Steel System
Regulation Number: 21 CFR 888.3010
Regulation Names: Bone fixation cerclage.
Regulatory Class: II
Product Code: JDQ
Dated: August 01, 2008
Received: August 04, 2008

Dear Ms. Elias:

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

Indications for Use

510(k) Number (if known): K081622

Device Name:

Abbott Spine Universal Clamp® Stainless Steel System

Indications for Use:

The Universal Clamp Stainless Steel System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone factures. The indications for use include, but are not limited to, the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions;

The Universal Clamp Stainless Steel System may also be used in conjunction with other medical implants made of stainless steel whenever "wiring" may help secure the attachment of other implants.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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 Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081622