K062391

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

SEP 14 2006

A.	Company Name:	Triage Medical, Inc
B.	Company Address:	13700 Alton Parkway Suite 160 Irvine, CA 92618
C.	Company Phone:	(949) 472-0006
D.	Company Facsimile:	(949) 472-0016
E.	Contact Person:	Gayle Hirota Manager, Quality Assurance & Regulatory Affairs

DEVICE IDENTIFICATION

A.	Trade Name:	Disposable Posterior Lumbar Stabilization Procedure Kit and Re-usable Compression Tool
B.	Catalog Number:	9045-01, 9045-02 and 6113-00
C.	Common Name:	Facet Screw and associated manual surgical instruments
D.	Classification Name:	Unclassified, various manual surgical instruments
E.	Product Code:	MRW, HXI, HTW, HXX, HWB, HWX, MJG, HWN
F.	Device Panel:	Orthopedic and General and Plastic Surgery
G.	Device Class:	Class II

IDENTIFICATION OF MODIFIED DEVICE

The Disposable Posterior Lumbar Stabilization Procedure Kit is similar in design and intended use to the Triage Medical BONE-LOK® 4.5mm Facet Screw and BONE-LOK® FS Instrument Kit cleared under 510(k) K043351.

DEVICE DESCRIPTION

The 4.5mm Facet Compression Device(s) contained in the Disposable Posterior Lumbar Stabilization Procedure Kit is a double-helix screw with a compression-locking collar and self-retaining washer. It is available as 4.5mm diameter device and is obtainable in a 30-40mm length range. Disposable surgical instruments for use in implanting the device are

also included in the kit. The kit is provided "STERILE"; sterilization is by gamma radiation. The re-usable Compression Tool is provided separately in a "NONSTERILE" condition; sterilization is by moist heat (steam autoclave) and is performed on-site.

INDICTIONS FOR USE

The 4.5mm Facet Compression Device with Washer, which is included in the Disposable Posterior Lumbar Stabilization Procedure Kit, is indicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by back pain of discogenic origin as confirmed by radiographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis or failed previous fusion.

INTENDED USE

The intended use of the 4.5mm Facet Compression Device contained in the Disposable Posterior Lumbar Stabilization Disposable Kit is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft at single or multiple levels from L1 to S1. The intended use of the associated manual surgical instruments is to aid in the implantation of the 4.5mm Facet Compression Device.

TECHNOLOGICAL CHARACTERISTICS

The 4.5mm Facet Compression Device contained in the Disposable Posterior Lumbar Stabilization Procedure Kit is identical to the previously cleared BONE-LOK® 4.5mm Facet Screw. The manual surgical instruments are substantially equivalent to the instruments cleared as the BONE-LOK® FS Instrument Kit.

BIOCOMPATIBILITY AND PERFORMANCE DATA

The 4.5mm Facet Compression Device is made of a titanium alloy, which meets the requirements of ASTM F-136. The materials for the devices as well as the instruments are identical to materials used in a myriad of legally marketed orthopedic spinal fixation devices and instruments.

Performance test results indicate that the device is safe and satisfies functional and performance requirements when used as indicated. The associated instruments have also met functional and performance requirements.

CONCLUSIONS DRAWN FROM STUDIES

Test results demonstrate that the devices contained in the Disposable Posterior Lumbar Stabilization Procedure Kit is substantially equivalent to the predicate devices and are capable of safely and effectively performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2006

Triage Medical, Inc.
% Ms. Gayle Hirota
Manager, Quality Assurance and Regulatory Affairs
13700 Alton Parkway, Suite 160
Irvine, California 92618

Re: K062391
Trade/Device Name: Disposable Posterior Lumbar Stabilization (PLS) Procedure Kit
Regulation Name: facet screw spinal device system
Regulatory Class: Unclassified
Product Code: MRW
Dated: August 14, 2006
Received: August 16, 2006

Dear Ms. Hirota:

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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchmd

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): K062391

Device Name: Disposable Posterior Lumbar Stabilization (PLS) Procedure Kit

Indications For Use: The 4.5mm Facet Compression Device, which is included in the Disposable Posterior Lumbar Stabilization Procedure Kit, is indicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by back pain of discogenic origin as confirmed by radiographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis or failed previous fusion.

The intended use of the 4.5mm Facet Compression Device is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint and into the pedicle. The 4.5mm Facet Compression Device is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels from L1 to S1. The intended use of the associated manual surgical instruments is to aid in the implantation of the 4.5mm Facet Compression Device.

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)

Barbara Bucknor for MKM

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

510(k) Number K062391