510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K043351

SUBMITTER INFORMATION

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:	4.5mm BONE-LOK® Facet Screw
B.	Catalog Number:	TFCD-45-3040S / TFCD-45-3040N (Titanium alloy) SFCD-45-3040S / SFCD-45-3040N (Stainless steel)
C.	Common Name:	Facet screw
D.	Classification Name:	Unclassified
E.	Product Code:	MRW
F.	Device Class:	Class II (per 21 CFR 888.3030)

IDENTIFICATION OF PREDICATE DEVICE

The 4.5mm BONE-LOK® Facet Screw is similar in basic design, materials and intended use to the NuVasive™ Triad™ Facet Screw System cleared under 510(k) K020411.

DEVICE DESCRIPTION

The 4.5mm BONE-LOK® Facet Screw is a double-helix screw with a compression-locking collar and a self-retaining washer. It is available as a 30-40mm range device fabricated from either stainless steel, which meets the requirements of ASTM F-138, or Titanium 6Al-4V, which meets the requirements of ASTM F-136.

INDICATIONS FOR USE

The 4.5mm BONE-LOK® Facet Screw 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 BONE-LOK® Facet Screw is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The 4.5mm BONE-LOK® Facet Screw is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels from L1 to S1.

TECHNOLOGICAL CHARACTERISTICS

The 4.5mm BONE-LOK® Facet Screw is similar in materials, design, construction and mechanical performance to the predicate devices.

PERFORMANCE DATA (NON-CLINICAL)

Mechanical and biomechanical testing have established that the devices satisfies functional performance requirements and is safe when used as indicated.

BIOCOMPATIBILITY

The 4.5mm BONE-LOK® Facet Screw is made from either surgical grade Stainless Steel, which meets the requirements of ASTM F-138, or Titanium 6Al-4V ELI, which meets the requirements of ASTM F-136. These materials are currently being utilized in a myriad of legally marketed orthopedic devices.

CONCLUSIONS DRAWN FROM STUDIES

Literature, other documentation provided, and test results demonstrate that the 4.5mm BONE-LOK® Facet Screw is substantially equivalent to the predicate devices and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Ms. Gayle Hirota
QA/RA Manager
Triage Medical, Inc.
13700 Alton Parkway, Suite 160
Irvine, California 92618

Re: K043351
Trade/Device Name: 4.5mm BONE-LOK® Facet Screw
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: II
Product Code: MRW
Dated: February 1, 2005
Received: February 3, 2005

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.

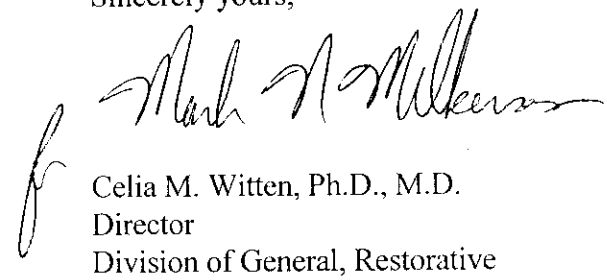
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 se 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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): K043351

Device Name: 4.5mm BONE-LOK® Facet Screw

Indications For Use:

The 4.5mm BONE-LOK® Facet Screw 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 BONE-LOK® Facet Screw 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 BONE-LOK® Facet Screw is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels from L1 to SI.

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)

for Mark N Milhous

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

510(k) Number K043351