MAR 2 3 2004

K040250

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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:	BONE-LOK™ HP Washer
B.	Catalog Number:	2057-00
C.	Common Name:	Washer
D.	Classification Name:	Washer, Bolt Nut
E.	Device Class:	Class II (per 21 CFR 888.3030)

IDENTIFICATION OF PREDICATE DEVICE

The Triage Washer is similar in design, materials, and intended use to the Synthes 13.0mm Washer and the Biomet Orthopedics Titanium Washer, 13mm.

DEVICE DESCRIPTION

The BONE-LOK™ HP Washer is intended for use with BONE-LOK™ HP Cannulated Helical Compression Anchor System in the general management of fractures and reconstructive surgery. The washer provides a bearing surface for the screw head against the bone and also prohibits migration of the screw head into the cortex.

The BONE-LOK™ HP Washer is fabricated from Titanium 6Al-4V ELI, which meets the requirements of ASTM-136.

The BONE-LOK™ HP Washer is provided "NON-STERILE" and will require subsequent sterilization on site. The BONE-LOK™ HP Washer will be supplied as a part of the BONE-LOK™ HP Instrument Kit or as individual units packaged in a labeled poly bag. The Instrument Kit is distributed in a custom autoclavable compartmentalized tray with a locking lid. Both the BONE-LOK™ HP Washer and the Instrument Kit may be sterilized by moist heat. The sterilization validation method is in conformance with international standards (EN 554 and ISO/ANSI/AAMI 11134). Sterilization instructions are included in the Instructions for Use.

INTENDED USE

The BONE-LOK™ HP Washer is intended for use with the BONE-LOK™ HP Cannulated Helical Compression Anchor System in the general management of fractures and reconstructive surgery.

TECHNOLOGICAL CHARACTERISTICS

The BONE-LOK™ HP Washer is similar in basic materials, design, construction and mechanical performance to the predicate devices.

PERFORMANCE DATA

The sole function of the BONE-LOK™ HP Washer is to provide a bearing surface for the screw head against the bone and prohibit migration of the screw head into the cortex. Because the washer is fabricated from a material with specified mechanical requirements, is of limited functionality, and washers have been previously utilized in this capacity, additional testing is not required.

BIOCOMPATIBILITY

The BONE-LOK™ HP Washer is made from Titanium 6Al-4V ELI, which meets the requirements of ASTM-136. This material is currently being utilized in a myriad of legally marketed devices. Because its inertness and biocompatibility has already been established, additional testing is not required.

CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the BONE-LOK™ HP Washer 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

MAR 2 3 2004

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

Re: K040250
Trade/Device Name: BONE-LOK™ HP Washer
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: January 27, 2004
Received: February 2, 2004

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.

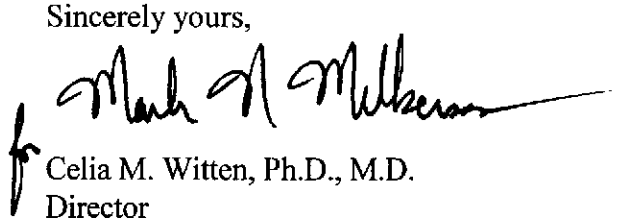
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



for 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: K040250

Device Name: BONE-LOK™ HP Washer

Indications for Use: The BONE-LOK™ HP Washer is an accessory intended for use with the BONE-LOK™ HP Cannulated Helical Compression Anchor System, in the general management of fractures and reconstructive surgery.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous

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

510(k) Number K040250