510(k) SUMMARY
of Safety and Effectiveness Information

In accordance with the Food and Drug Administration Rule to implement provisions of the safe Medical devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Aequalis Shoulder Fracture System.

Manufacturer: TORNIER, S.A.
Rue du Doyen Gosse
38330 SAINT-ISMIER / France
Registration No : 9610667

US Representative: Mr. David W. SCHLERF
BUCKMAN Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

Date: September 2, 1999

Contact Person: Anne LE ROUZO
Regulatory Affairs Manager

Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis - 21CFR888.3660

1. Classification:

§888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis. (a) Identification. A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as Titanium or cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§888.3027). (b) Classification. Class III. (c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §888.3.

The Orthopedic and Rehabilitation Devices Panel assigned the unique device classification Product Code **87KWS** to this device.

2. Voluntary standard:

Various voluntary performance standards are utilized. They include Tornier, S.A. Standard Operating Procedures (SOP), vendor certifications and qualification procedures, Quality System Regulations (QSR), ISO9001 & EN46001 specifications, and European CE Marking.

3. Labeling / Packaging:

Labeling complies with all FDA requirements in effect at the time of device review and clearance. Warning and caution statements are displayed as appropriate. Professional information is available from Tornier and is supplied with all product ordered. Please obtain and review all product information before using the system. Only the information supplied with the product is to be considered current and complete.
The Aequalis Shoulder Fracture System offers all components in double blister-type peel packs. This is an industry typical package obtained from commercial suppliers of such packaging.

4. Device Description:

Overview. The usual goal of total shoulder replacement and hemi-arthroplasty of the shoulder is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The *Aequalis Shoulder Fracture System* is intended to accomplish these goals. With the *Aequalis Shoulder Fracture System*, the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury. Though the *Aequalis Shoulder Fracture System* is intended for use as a total shoulder replacement system, or as a hemi-shoulder. The modular nature of the system allows for the later conversion of a primary hemi-arthrosplasty to a total shoulder replacement.

Device Description. The *Aequalis Shoulder Fracture System* is a typical 3 part system consisting of interchangeable humeral heads, a humeral stem and, if used as a total shoulder, a glenoid component.
The *Aequalis Shoulder Open stem for Fracture* is available in 3 diameters (6.5, 9 and 12), with the same length. The geometry of the metaphyseal part has been designed to allow the filling by bone graft and to improve the knitting of the bones. The goal of the metaphyseal shape is to make a "bony bridge" between the tuberosities. In order to allow extraction of the prosthesis in case of revision, two slits have been designed to break the bony bridge. Anterior-posterior fins extending from diaphyseal portion form a convex bearing area allowing adequate positioning and synthesis of the greater tuberosity. The stem is used cemented in the diaphyseal part.

Various heads may be assembled to the stem in different configurations thus accommodating large variations in patient size and anatomy. The head is fixed on the stem on a Morse taper. It is impacted onto the stem on an impacting support. Subsequent revisions may be accomplished if necessary by reoparetion and separation of the head and the stem. The taper fit heads may be rotated about the axis of the Morse taper. The reverse surface of the heads has series of holes drilled around the female Morse taper every 45°. Because the female Morse taper of the head is eccentric, rotation of the head before fully seating the male and female tapers produces eight possible offset combinations for the orientation of the humeral head radius. The rotational adjustability of the humeral articulating surface expands the surgical flexibility of the system.
The articulating surface of each head is designed to mate with either the natural glenoid (hemi-shoulder applications) or the available glenoid implants (total shoulder applications).

The Aequalis glenoid components are pear-like in shape, to avoid friction with the deep surface of the rotator cuff.

Open Stem for fracture: 3 dia. (6.5, 9 and 12 mm) with 1 length

Humeral Heads:	37mm x 13.5mm	50mm x 16mm
	39mm x 14mm	50mm x 19mm
	41mm x 15mm	52mm x 19mm
	43mm x 16mm	52mm x 23mm
	46mm x 17	54mm x 23mm
	48mm x 18mm	54mm x 27mm

Glenoid: 3 sizes (small, medium, large)

Each component of the system is individually part coded for ease identification. The offered combinations of stem, head and glenoid sizes accommodate a wide range of anatomical variations and circumstances.

Contraindications and Cautions. Only surgeons fully experienced in total and hemi-arthroplasty surgical technique of the shoulder should utilize the device. Please contact Tornier about available instructional course demonstrations and bio-skills workshops.

5. Packaging and Sterilization Information:

The prostheses are supplied sterile from Tornier. The technique used to achieve the sterilization is known as gamma radiation sterilization. A radiation dose of at least 2.5 Mrad is utilized. The sterility assurance level (SAL) is 10^{-6}. The validation of the sterilization has been carried out according to the standard EN552.
The implant is contained in a double sealed blister pack in order to maintain sterility. Once the packaging is opened, the implant must never be resterilized. In case of packaging is damaged, the implant must be rejected.

The instruments required to properly use the device are provided non-sterile. They must be decontaminated, cleaned and sterilized prior to each surgery. All packaging, labeling and shipping materials must be removed from the instruments prior any operation. The recommended sterilization method is steam sterilization at 274°F for 18 minutes.

6. Summary of Safety and Effectiveness Information.

This summary contains information upon which a determination of substantial equivalence could be based. Selected device testing demonstrates the functional equivalence of the Aequalis Shoulder Fracture System. A feature comparison table is used to graphically present important parameters of the available systems. The comparison table is identified as Table 1, located after the Class III Summary section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

Mr. David W. Schlerf
Representing Tornier, S.A
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K994392
Trade Name: Æqualis® Shoulder Fracture System
Regulatory Class: III
Product Code: KWS
Dated: November 21, 1999
Received: December 28, 1999

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994392

Device Name: Æqualis® Shoulder Fracture System

Indications For Use:

Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint. Including humeral head fracture and displaced 3 or 4 part proximal humeral fractures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994392

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)