

K994393

**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 Universal Shoulder Glenoid.

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 23, 1999

Contact Person: Anne LE ROUZO
Regulatory Affairs & Quality 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.

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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 Universal Shoulder Glenoid 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:

Description. The *Aequalis Universal Shoulder Glenoid* is intended for cemented use as the glenoid component in total shoulder arthroplasty, completed using humeral components of the Tornier Aequalis Total Shoulder System. The *Aequalis Universal Shoulder Glenoid* is manufactured in four sizes from Ultra High Molecular Weight Polyethylene (UHMWPE). The component's articulating (or lateral) surface is concave and is designed to articulate with the head of an existing, commercially available Tornier Aequalis Shoulder humeral prosthesis. The *Aequalis Universal Shoulder Glenoid* articulating surface has a radius of curvature greater than the corresponding humeral head. This mismatch between the glenoid and the humeral head is intended to allow the translation of the head in the superior/inferior and anterior/posterior directions.

The back surface of the *Aequalis Universal Shoulder Glenoid* is spherical in geometry, in order to conform to the geometry of the glenoid fossa. It is grooved in order to increase the interface glenoid implant / bone cement.

The back (or medial) surface of the component has either a keel or four pegs for fixation in the glenoid. These glenoid components are 4 mm thick and available in four sizes (small, medium, large and X-large) for each component, the keeled and pegged components.

- The *Aequalis Universal pegged Glenoid* features one centrally located peg and three peripheral pegs placed in a triangular configuration. The peripheral pegs are fitted with transversal grooves that provide enhanced cement fixation. The three peripheral pegs provide resistance to rocking and rotational motion caused by translation of the prosthetic humeral head. The central peg features an X-ray marking wire in Cobalt-Chromium alloy.
- The *Aequalis Universal keeled Glenoid* features a centrally located keel to provide translational and rotational stability of the implant. A groove around the middle of the keel provides enhanced cement fixation. The keel features an X-ray marking wire in Cobalt-Chromium alloy.

Materials. The *Aequalis Universal Shoulder Glenoid* is manufactured from implant grade ultra-high molecular weight polyethylene (UHMWPE) according to ISO5834-2, with a small Cobalt-Chromium wire included as an opaque radiographic marker.

Indications. The *Aequalis Universal Shoulder Glenoid*, in conjunction with their corresponding humeral component, are intended for total shoulder arthroplasty. The indications for use are as follows:

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Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the gleno-humeral joint; non-union humeral head fracture; displaced 3 and 4 proximal humeral fractures; avascular necrosis of the humeral head; or other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable.

Contraindications and Cautions. Only surgeons fully experienced in total 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 Universal Shoulder Glenoid. 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.

7. Class III Certification

Tornier, S.A. certifies that a reasonable search of all information known or otherwise available to Tornier, S.A. about the types and causes of reported safety and/or effectiveness problems for total shoulder prostheses has been conducted. Tornier, S.A. further certifies that the types of problems to which the *Aequalis Universal Shoulder Glenoid* is susceptible and their potential causes are listed in the following Class III summary, and that this Class III summary is complete and accurate.

8. Class III Summary

The most frequently reported problems associated with shoulder glenoid implant fall into two basic groupings, procedure related and device related.

Of the procedure related risks, infection, vascular injury, nerve injury and bony trauma are most often reported. Since the *Aequalis Universal Shoulder Glenoid* is intended to be implanted only by qualified orthopedic experts and utilizes the basic surgical technique and fixation methods as the

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other devices, procedure related adverse events can reasonably be expected to be equivalent in occurrence.

Of the reviewed device related events, disassociation of one or more of the system components are the most frequently cited complications. A few isolated intra-articular wear debris and device loosening reports were also noted as case reports in the literature.

Glenoid component failures typically occur in devices made of a metal tray and a polyethylene insert. The polyethylene insert may be sheared away or unsnapped from the cemented metallic base. Since the *Aequalis Universal Shoulder Glenoid* uses a glenoid component made completely from polyethylene, this particular type of failure cannot occur. Disassociation of polyethylene glenoid components does occur and is mostly related to failure of the cement mantle and/or an extraordinary post-surgical traumatic event. The *Aequalis Universal Shoulder Glenoid* will be subject to such glenoid failure. Cement interface failure and traumatic glenoid failure may be expected to occur in much the same way and frequency as other shoulder systems.

Device loosening is primarily related to cement/bone or cement/implant failure. The frequency of this occurrence on the glenoid is related to site preparation, technique and handling of the bone cement. It is not expected that the occurrence of this particular adverse event will be any higher or lower when using the *Aequalis Universal Shoulder Glenoid*.

Medical Device Reporting (MDR) experience for the *Aequalis Universal Shoulder Glenoid* is unknown because United States distribution of the System has not occurred as of the date of this summary.

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TABLE 1 / Comparison table:

Feature or System Characteristics	TORNIER Aequalis Universal Shoulder Glenoid	TORNIER Aequalis Shoulder System	SULZER Orthopedics Anatomica Glenoid Component	DEPUY Global Shoulder Glenoid	OSTEONICS All-Polyethylene Glenoid Shoulder Component	INTERMEDICS Select Shoulder Keeled All-Poly Glenoids	INTERMEDICS Select Shoulder Pegged All-Poly Glenoids	ENCORE Glenoid component for the Foundation Total Shoulder System	SE?
Materials									
	UHMWPE	Same	Same	Same	Same	Same	Same	Same	Yes
Method of Fixation									
	Cemented	Same	Same	Same	Same	Same	Same	Same	Yes
Keel or Pegs	Keel / Pegs	Keel	Pegs	Pegs	Keel	Keel	Pegs	Keel / Pegs	Yes
Indications for Use									
	Total Shoulder replacement	Same	Same	Same	Same	Same	Same	Same	Yes
Standards Specifications									
UHMWPE	ISO 5834-2	Same	ASTM F 648	ASTM F 648	ASTM F 648	ASTM F 648	ASTM F 648	ASTM F 648	Yes
K-number									
	PENDING	K952928 & K980244	K990136	K981487	K962082	K962238	K962244	K960906	-



JUN 22 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994393
Trade Name: *Æqualis*[®] Universal Shoulder Glenoid
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.

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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,



dr 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 **K994393**

Device Name: **Æqualis® Universal Shoulder Glenoid**

Indications For Use:

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; non-union humeral head fracture; displaced 3 and 4 part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable.

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 12974357

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____