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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

aap Implantate AG

Submitters Name: *aap* Implantate AG
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DEC - 7 2004

Contact Name: Marc Seegers, Director Quality Management
email: m.seegers@*aap*.de

Name of Device: ÆQUOS Knee Endoprosthesis cemented

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Common/Usual Name: Knee-Endoprosthesis

Proprietary Name: ÆQUOS-Knee- Endoprosthesis

Device Class: Class II

Product Code: 87 J WH

Classification: CFR Chapter I, Title 21 § 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Review Panel: Orthopaedics

Performance Standards:

Devices are manufactured according to cGMP's, applicable ASTM requirements, and applicable harmonised standards ISO 9001 / EN 46001.

Material Composition:

ÆQUOS- Knee- Endoprosthesis components are manufactured of Cobalt Chromium Alloy (ASTM F75) and Ultra-High Molecular Weight PolyEthylene (ISO 5834-2)

Intended Use:

ÆQUOS- Knee- Endoprosthesis is intended to provide mobility and reduce pain by replacing the damaged knee joint articulation. Candidates for total knee joint includes patients with a severely painful and/or severly disabled joint resulting from different syndromes.

The indications are:

- Damaged and seriously damaged and painful knee joints with relevant malfunction, instability or subluxation of the joint
- Therapy resistant bow contracture of more than 20° or non compensable malposition of the anatomical axis from approximatly 15-20°
- Double sided joint anchylosis or anchylosis of the opposite hip joint

- All conservative therapies were unsuccessful or joint conserving operations provide no success or have already failed
- Failure after implantation of monocondylar implants
- Stiffening of the joint is contraindicated

The contra-indications are:

- Badly condition of the patient
- Badly condition of the skin
- Untreated malfunction of the metabolism
- Joint destruction caused by haemophilia, tabes or after infections
- Instability of the joint ligaments

The ÆQUOS knee endoprosthesis is only for use with bone cement

Device Description:

The ÆQUOS knee endoprosthesis consists of:

a) Femoral components in anatomic and asymmetrical design manufactured from cast CoCr alloy (ASTM F75).
Femoral components are intended for cemented use only.

b) Tibial baseplate in anatomic design manufactured from cast CoCr alloy (ASTM F75).
The tibial baseplate is a non-porous, stemmed configuration and intended for cemented use only.

c) Tibial inserts in anatomic and asymmetrical design manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE)

d) Tibial spacers

Predicate Devices for Substantial Equivalence:

ÆQUOS is similar in size, material and intended use to the

- Anatomic Total Knee (k000978) of Biomet, Inc.
- Columbus (CR) Total Knee System (k023788) of Aesculap, Inc.
- Nexgen Complete Knee Solution – Trabecular Metal (k024161) of Implex Corp.
- Maxim Accel Knee System (k023546) of Biomet, Inc.

Comparision of Technological Characteristics: Æquos is substantially equivalent to the predicate devices with respect to physical/technical and material characteristics.

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Sterilisation Information:

The ÆQUOS Knee- Endoprosthesis are distributed in sterile condition.

The instruments and implants provided in non-sterile condition must be decontaminated, cleaned and sterilised prior to each surgery. All packaging materials must be removed.

Recommendations for sterilisation are contained in the package insert.

Note: These devices are sterilised by end users utilizing the approved/outlined guidelines found in the AAMI Guideline "Good Hospital Practice: Steam Sterilisation and Sterility Assurance" and in ANSI/AAMI/ISO 11737 guidelines to achieve the acceptable Sterility Assurance Level (SAL).

Devices which are available in sterile condition are sterilised with gamma radiation sterilisation. A radiation dose of at least 2.5 Mrad is utilized. The sterility assurance level (SAL) is 10^{-6}. The validation has been carried out according to the standard ISO 11137.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 2004

Mr. Marc Seegers
Director Quality Management
aap Implantate AG
Lorenzweg 5
12099 Berlin
Germany

Re: K033260
Trade/Device Name: ÆQUOS Knee Endoprosthesis
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: November 26, 2004
Received: November 29, 2004

Dear Mr. Seegers:

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.

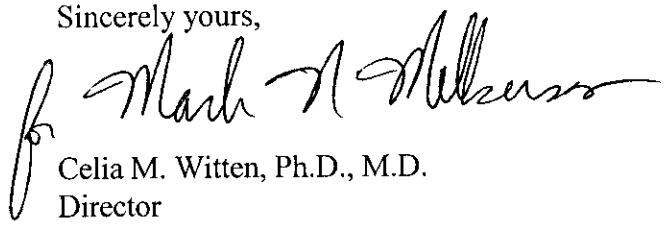
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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Indications for Use Statement

510(k) Number (if known): K033260

Device Name: ÆQUOS Knee Endoprosthesis

Indications for Use:

- Damaged and seriously damaged and painful knee joints with relevant malfunction, instability or subluxation of the joint
- Therapy resistant bow contracture of more than 20° or non compensable malposition of the anatomical axis from approximatly 15-20°
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- All conservative therapies were unsuccessful or joint conserving operations provide no success or have already failed
- Failure after implantation of monocondylar implants
- Stiffening of the joint is contraindicated

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

Mark N Milhozer

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

510(k) Number K033260