JUL 2 9 2002 K020222 Page 1 of 2

11. SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

WISORB™ MALLEOLAR SCREW

SUBMITTER'S NAME AND ADDRESS: CAMBRIDGE SCIENTIFIC INC.,
180 FAWCETT STREET,
CAMBRIDGE, MA 02138

CONTACT NAME: DEBRA J. TRANTOLO, PH. D, PRESIDENT AND CEO
CAMBRIDGE SCIENTIFIC, INC.
(PHONE: 617–576–2663; FAX: 617–547–2663;
E-MAIL: DTRANTOLO@AOL.COM).

Date Prepared: January 2, 2002

NAME OF DEVICE: **WISORB™ MALLEOLAR SCREW**

Classification name: The classification name of the device is "smooth or threaded bone fixation fastener" as per FDA 21 C.F.R •888.3040.

Proposed regulatory class: The WISORB™ malleolar screw is classified into class II.

Product code: The code of the intended device is 88HWC–Bone Fixation Screw.

Predicate Devices:

1. Biofix® Bioabsorbable Self-reinforced Poly-L-Lactide, Fixation Threaded Rod (K952471)
2. Biofix® Bioabsorbable Poly(Glycolic Acid), Threaded Rod (K920188)
3. Biofix® Bioabsorbable Distal Radial Screw (K974876)

Int nded Uses: The WISORB™ malleolar screw is intended for use in bone-to-bone fixation in the metaphyseal area, distal humerous, trochanteric area, and in the ankle where the bone is dense.

The WISORB™ is intended primarily for internal fixation of fractures with minimal displacement commonly seen in fractures of the ankle and foot, such as, transverse fibular fractures at, or distal to the ankle joint including fractures of the lateral, medial and posterior malleolus. The WISORB™ is intended for single use only.

Devic De cription:

The WISORB™ malleolar screw is composed of 75% by wt (88% by volume) of the copolymer (L -co-D,L-lactide) (weight ratio 70:30), and 25% by wt (12% by volume) of sintered hydroxylapatite. The WISORB is a bioabsorbable, partially-threaded screw with a conical head and rounded bottom.

The WISORB™ has a single size with the following dimensions:

i. Length 30 mm
ii. Thread diameter 4.5 mm
iii. Thread length 11.64 mm
iv. Shaft diameter 2.62 mm
v. Head diameter 6.75 mm
vi. Head depth 6.73 mm

Substantial Equivalence:

The WISORB™ malleolar screw is substantially equivalent to other cleared bioabsorbable, internal fixation devices such as threaded rods and screws used in the fixation and maintenance of alignment of cancellous fractures of the malleolus and radius.

In vitro laboratory, mechanical testing and animal studies have been submitted that support the equivalence of the WISORB™ malleolar screw to other predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

Dr. Debra J. Trantolo
President and CEO
Cambridge Scientific, Inc.
180 Fawcett Street
Cambridge, Massachusetts 02138

Re: K020222
Trade/Device Name: Wisorb™ Malleolar Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 16, 2002
Received: May 17, 2002

Dear Dr. Trantolo:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 (If known): K020222

Device Name: WISORB™ malleolar screw

Indications for Use:

The WISORB™ malleolar screw is intended for use in bone-to-bone fixation in the metaphyseal area, distal humerous, trochanteric area and in the ankle where the bone is dense.

The WISORB™ malleolar screw is intended primarily for internal fixation of fractures with minimal displacement commonly seen in fractures of the ankle and foot, such as, transverse fibular fractures at or distal to the ankle joint (Danis-Weber Type A); low spiral fractures of the lateral malleolus, avulsion fractures of the medial malleolus (Dyputren; Danis-Weber Type-B), avulsion fractures of the posterior malleolus (Volkmann's Triangle). Other fractures that maybe suitable for treatment with the WISORB™ malleolar screw include distal radial fractures (Type Colles), which typically occur at the metaphyseal portion of the bone proximal to the extensor tendon sheaths.

The WISORB™ malleolar screw is not intended for use in and is contraindicated for:

- Fractures of cortical bone (diaphyseal area)
- Situations of active or potential infection or where patient cooperation cannot be guaranteed.

(Please do not write below this line—Continue on other page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes **OR** **Over-the Counter Use** No

(Per 21 CFR 801.109)

for Mark N Melkerson

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

510(k) Number K020222