MAY 2 0 2003

K030518

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. May 30, 2002. [Separate Page]

I.* Submitter: Greg Wiita, Amertek Medical, Inc., 2655 North Ocean Drive, Singer Island, Florida 33404.

II. Classification Names and numbers: Acc. to Ultrasound Probe: Stepping Device, Code ITX; brachytherapy template, Code ITX.

III. Common/Usual Name: Stepping and Stabilization Device, and template

IV. Proprietary Names: Amertek™ Sure-Point Tracker System

V. Establishment Registration Number: 1066424

VI. Classification: Accessories to ultrasonic transducer, Class II, CFR 892.1570

VII. Substantial Equivalence: Amertek™ is substantially equivalent (and nearly identical to) its predecessor devices cleared under K-972152 and K-011581. It is also equivalent to devices cleared for marketing by the 510(k) process under K-000960 (Barzell-Whitmore), K-864807 (Teknar), K-871413 (Civco), K-913293 (Mick Radio-Nuc.), K-961303 (Life Imaging Systems), K991517 (Galil Medical), K-881605 (Teknar Corp.), K-003270 (Nucletron Corp.) and K-963302 (Tayman Medical).

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended uses, as the classified device and those cleared for marketing as equivalent to it by the 510(k) process under K972152 (Devmed, Inc.), K011581 (Amertek Inc.), K802032 and K913293 (Mick Radio-Nuclear), under K864807 (Teknar Corp.) and others listed above.

2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market.

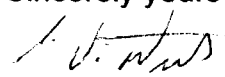
3. Descriptive information provided shows that the materials from which Amertek™ is made are substantially equivalent those of similar products, used for identical purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment VI.

(End of Summary)

We have not found a specific guidance document on this subject, but believe we have complied fully with general guidance documents and usual practices in preparing premarket notifications. We have followed the software guidance document, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" issued Jan. 11, 2002. If additional information or explanation is needed, please call me at 800-533-2823 or fax me at 561-842-6660. Alternately, you may contact Dr. H. N. Dunning at 301-229-2138, for a local response.

Sincerely yours



Greg Wiita
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Mr. Greg Wiita
President
Amertek Medical, Inc.
2655 North Ocean Drive
SINGER ISLAND FL 33404

Re: K030518
Trade/Device Name: Amertek™ Sure-Point Tracker System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: February 10, 2003
Received: February 19, 2003

Dear Mr. Wiita:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VIII.1 Indication for use. [Separate page].

510(k) number: N/A K030518

Device Name: Amertek Sure-Point Tracker™

The major intended use of the Amertek Sure-Point Tracker™ is the same as that of its unmodified predecessors cleared in K011581 and K972152: to allow precision ultrasound probe alignment and radioactive seed implantation in brachytherapy treatments. A specific application is the treatment of prostate (or other) cancer. The Amertek Sure-Point Tracker™ also allows data from the use of probe location indicators to be fed directly into the brachytherapy planning program, such as that of Varian.

Like other basic stabilizers and steppers (e.g. Barzell-Whitmore Omnistand; Tayman Accuguide; Teknar, Proscan), this device is applicable in other surgical procedures or specialties which require accurate instrument fixation, such as cryosurgery, biopsy, and remote afterloading equipment (HDR) such as that used with the Nucletron device.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030518

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use √ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)