3/5/99

K984382

Section 9 - Summary of Safety and Effectiveness

Date of Preparation: 9/5/98

Device Name: Tayman Medical Inc., AccuGuide

Classification Name: Biopsy Guide, 1YO

Manufacturer: Tayman Medical
743 Spirit 40 Park Drive, Suite 112
Chesterfield, MO 63005
(800) 859-0525

510(k) Submitter Tayman Medical
743 Spirit 40 Park Drive, Suite 112
Chesterfield, MO 63005
(800) 859-0525.

Contact Person: James Taylor

Predicate Device: This device is substantially equivalent to the Teknar, Inc. Biopsy Needle Guide Attachments, manufactured by Teknar Corporation located at 1279 Maurer Industrial Drive, St. Louis, MO 63127. This device was the subject of Premarket Notification K881605.

Device Description: Tayman Medical Inc., AccuGuide comprises a steel spring mounting clip, a stainless steel mounting tab and a stainless steel biopsy needle guide tube.

Intended Use:

The Tayman Medical Biopsy Guide is used to ensure the appropriate placement of the biopsy needle for exact tissue sampling during ultrasonically guided diagnostic biopsy procedures.

The Tayman Medical AccuGuide is used in conjunction with currently available CLI 4900 Ultrasound Probe manufactured by Capistrano Labs and 18 gauge x 20 centimeter automated biopsy needles. Such as:

HRI 2000 manufactured by International Ultrasound 14 West Forest Avenue, Englewood, NJ 07631 and

Ultra-Cut Automated Biopsy System manufactured by Medical Device Technologies 4445 S.W. 35th Terrace, Suite 310, Gainesville, FL 32608.

Clinical and Non-Clinical Similarities and Differences:

The Tayman Medical AccuGuide is constructed of stainless steel and medical grade hard chrome plated steel.

The Teknar Biopsy Guide is constructed of stainless steel.

Teknar manufactures two basic variants of the Accu Guide Biopsy Guide, with rails and without rails. There is no functional difference between the two, they are offered to accommodate different biopsy needles. The Tayman Medical AccuGuide is offered in the without rails variant only.

The Tayman Medical AccuGuide is comprised of three basic components: the probe clamp, the mounting tab, and the biopsy needle guide tube.

Probe Clamp - the probe clamp is made of medical grade hard chrome plated steel it provides a spring force to hold the Tayman Medical AccuGuide to the ultrasound probe. The probe clamp does not contact the patient.

Mounting Tab – the mounting tab is made of stainless steel. It provides a common joining point for the other components and acts as a stabilizer between the Tayman Medical AccuGuide and the ultrasound probe. The mounting tab does not contact the patient.

Biopsy Needle Guide Tube - the biopsy needle guide tube is made of stainless steel. It guides the needle along the predetermined path. This component contacts intact tissue. This component is designed in a low profile with a smooth, rounded tip.

The predicate device, the without rails variant of Teknar Accu Guide, is comprised a mounting ring and the biopsy needle guide tube.

Mounting Ring - the mounting ring attaches to the ultrasound probe by tightening a thumbscrew. This function duplicates the spring mounting feature of the Tayman Medical AccuGuide. The Mounting ring also serves to stabilize the guide and provide a common joining point for the other components. This function duplicates the mounting tab of the Tayman Medical AccuGuide. The mounting ring does not contact the patient.

Biopsy Needle Guide Tube - the biopsy needle guide tube is made of stainless steel. It guides the needle along the predetermined path. Its function is identical to that of the biopsy needle guide tube of the Tayman Medical AccuGuide. This component contacts intact tissue.

The Tayman Medical Standard Biopsy Needle Guide is biocompatible with the body tissue that it contacts as it is made of the same materials as the predicate device in the patient contact areas. The device is sterilized using steam cycles, which have been validated by the overkill method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

James Taylor
Vice President
Tayman Medical
743 Spirit 40 Park Drive Suite 112
Chesterfield, MO 63005

Re: K984382
Tayman Medical AccuGuide
Dated: September 13, 1998
Received: December 8, 1998
Regulatory class: II
21 CFR 892.1560/Procode: 85 IYO

Dear Mr. Taylor:

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 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). 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 (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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8 - Indications for Use Statement

510(k) Number(if known): K984382

Device Name: Tayman Medical AccuGuide

Indications for Use: Tayman Medical AccuGuide is used to mount disposable 18 gauge x 20 centimeter automated biopsy needles to the CLI 4900 Ultrasound Probe manufactured by Capistrano Labs for the purpose of accurately guiding the needle to the site where the biopsy sample is to be taken.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984382