K023637
page 1 of 2

510(K) SUMMARY FEB 2 6 2003

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: **Tytan Medical Corp.**

Address: 1F, No. 2, First Lane, Juang Shing Rd., 1 , Wu Gu, Taipei, 248, Taiwan, R.O.C.

Phone: 886-2-8988-3828

Fax: 886-2-8981-2254

Contact: Michael Shieh

2.0 Device Name: **Tytan Model # 600 series Electronic Stethoscope**

Model no.: 6XY (X,Y = 0-9, A-Z, or blank)

* The first Character (0-9, A-Z, or blank)is for the **minor change** revision of device (The Minor change meaning device change that do not affect the conformity test result of EMC & Safety, ie. IEC 60601-1 and IEC 60601-1-2)
* The second Character(0-9, A-Z, or blank) is for the color of the device (for example 0 for Black housing & tubing)

Tytan #600 Electronic Stethoscope is the 1st revision design of Black housing & tubing

3.0 Classification: Class II

4.0 Predicate Device: **3M Littmann Model 2000 Electronic Stethoscope (K#961848)** marketed by **3M Health care**

5.0 Device Description: This electronic Stethoscope is used for the amplification of of heart, lung and other body sounds. This Stethoscope has 3 modes for selective frequency amplification & a 8-steps volume control.

6.0 Intended Use: The **Tytan Model # 600 series Electronic Stethoscope** is a diagnostic aid and used as part of a physical assessment of a patient by Health Care Professional. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency.

Performance Summary: In terms of performance specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 & related requirements.

8. Conclusions:

The **Tytan Model # 600 series Electronic Stethoscope** have the same intended use and similar technological characteristics as the **3M Littmann Model 2000 Electronic Stethoscope (K#961848)** marketed by **3M Health care**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Tytan Model # 600 series Electronic Stethoscope** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Tytan Medical Corp.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
3892 South America West Trail
Flagstaff, AZ 86001

Re: K023637
Trade Name: Tytan #600 Series Electronic Stethoscopes
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: February 10, 2003
Received: February 12, 2003

Dear Ms. Reich:

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 (301) 594-4646. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023637

510 (k) NUMBER (IF KNOWN): K023637

DEVICE NAME: **Tytan #600 Series Electronic Stethoscopes**
Tytan Medical Corp.

INDICATIONS FOR USE:

The **Tytan #6xy Series Electronic Stethoscope** is a diagnostic aid and used as part of a physical assessment of a patient by Health Care Professional. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use V (Per 21 CFR 801.109) OR Over-The-Counter _____ (Optional Format)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023637