DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2002

ANDROMED, Inc.
c/o Ms. Geneviéve Hamel
Director, Regulatory Affairs & Quality Assurance
4610 Bois-Franc Road
Saint-Laurent, Quebec
Canada H4S 1A7

Re: K022298
Trade Name: i-Stethos Link Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: July 12, 2002
Received: July 16, 2002

Dear Ms. Hamel:

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) 594-4646. 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,

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

Enclosure

Attachment A

Indications for Use Statement

510(k) Number: K022298

Device Name: i-Stethos Link Electronic Stethoscope

Indications for Use:

The i-Stethos Link Electronic Stethoscope is intended for the purpose of electronically amplifying and listening to biological sounds, such as those produced by the heart, lungs, arteries and veins, and other internal organs and systems. The i-Stethos Link may also be used to display the heart rate, which is calculated as the number of heartbeats per minute.

In addition, the i-Stethos Link is equipped with an analog I/O port to interface with external devices such as a computer and to accept input from other compatible devices such as the biological sound monitor (BSM) sensor or another i-Stethos Link.

The i-Stethos Link Electronic Stethoscope is indicated for use under the same conditions that would otherwise require the use of an acoustic (non-electronic) stethoscope.

The i-Stethos Link Electronic Stethoscope is not intended as a substitute for medical care or for diagnosis and treatment by unlicensed or unqualified persons.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022298

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)