K070550/S1
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Pre-Market Notification 510(k) Summary

1. Sponsor Information:

Koratek Company, LTD.
307, 4th Venture Building, Hoseo University
165 Sechul-ri, Baebang-myun
Asan-city, Chungnam, 336-795
Republic of Korea

Contact Person:	Bong Woo Lee
Contact Title:	President
Contact Phone Number:	82-41-549-5437
Contact Fax Number:	82-41-549-5438

NOV 0 6 2007

Date of Summary: February 20, 2007

2. Device Name and Classification:

Common and Usual Name:	Electronic Stethoscope
Proprietary Name:	AUSCO ES-3100
Classification Name:	Electronic Stethoscope (21 CFR § 870.1875(b))
Performance Standards:	No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug and Cosmetic Act.

3. Predicate Device(s):

3M™ LITTMANN® Electronic Stethoscope, Model 3000, K041934
3M™ LITTMANN® Electronic Stethoscope, Model 2000, K961848
American Diagnostic Corporation's, Model ADC 656 Electronic Stethoscope, K012304

4. Description of Device:

The AUSCO ES-3100 Electronic Stethoscope is a healthcare device that electronically filters and amplifies sounds of the heart, lungs, arteries, veins and other internal organs, and transfers them to the user's ears through an active speaker and passive sound tubes. The AUSCO ES-3100 provides two filter frequency modes for auscultation: Bell (20 to 200Hz) and Diaphragm (20 to 1000Hz).

The AUSCO ES-3100 incorporates electronics and embedded software, which controls all of the various features such as volume control, frequency mode selection, and automatic powering off of the stethoscope. Active high and low pass filtering circuits are employed to produce the bell and diaphragm frequency response modes that are used to listen to the heart, lungs and other body sounds, while reducing frictional noises.

The AUSCO ES-3100 does not employ any off-the-shelf-software.

The AUSCO ES-3100 uses two (2) AAA alkaline batteries.

5. Indications for Use:

The AUSCO ES-3100 Electronic Stethoscope is intended for medical diagnostic purposes. It may be used for the amplification of sounds associated with the heart, lungs, arteries, veins, and other internal organs. It can be used on any person undergoing a physical assessment.

6. Comparative Data for Determining Substantial Equivalence to Predicate Device:

The similarities and differences of the AUSCO ES-3100 (new device) were compared to predicate devices (Littmann® models 2000 and 3000 and ADC 656). The proposed device under this new pre-market notification is similar in characteristics, materials, features, has similar performance features, intended use and indications for use as the Littmann® Model 2000 cleared under K961848 (September 26, 1997 clearance date), the Littmann® Model 3000 cleared under K041934 (October 15, 2004 clearance date) and American Diagnostic Corporation's ADC 656 electronic stethoscope cleared under K012304 (November 1, 2001 clearance date).

7. Non-Clinical Performance Summary:

Components of the AUSCO ES-3100 electronic stethoscope have been reviewed for biocompatibility and conform to ISO10993-Part 1 *Biological Evaluation of Medical Devices* for limited (≤ 24 hour) skin contact for direct patient exposure.

The AUSCO ES-3100 electronic stethoscope was tested and conforms to applicable safety and EMC requirements found in the IEC/ISO/EN 60601-01 and IEC/ISO/EN 60601-01-02 international standards.

8. Conclusions:

The AUSCO ES-3100 electronic stethoscope is similar if not identical in materials, technological characteristics, and has the same intended use as the predicate devices. Any differences in technological characteristics between the AUSCO ES-3100 and the predicate devices do not raise any new questions of safety or effectiveness.

We conclude that the AUSCO ES-3100 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

NOV 0 6 2007

Koratek Company, LTD.
c/o Mr. Paul Summer
Director, Regulatory and Quality Systems
Arkin Consulting Group
1733 Canton Lane
Marietta, GA 30062

Re: K070550
AUSCO ES-3100 Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: September 24, 2007
Received: September 26, 2007

Dear Mr. Summer:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K070550

4 Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): K070550

Device Name: AUSCO ES-3100 Electronic Stethoscope

Indications For Use:

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Prescription Use ___XX___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070550