K062364

510(k) SUMMARY

DEC - 6 2006

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information

US Agent:	Chong Kim 32936 Bluebird Loop Fremont, CA 94555
Official Correspondent:	Min-Kang Kim #1022 Sicox Tower, 513-14, Sangdaewon-Dong, Chungwon-Ku, Sungnam-Si, Kyunggi-Do, Republic of Korea
Sponsor:	Dongjin Medical Co., Ltd. #1022 Sicox Tower, 513-14, Sangdaewon-Dong, Chungwon-Ku, Sungnam-Si, Kyunggi-Do, Republic of Korea
Manufacturing Site	Dongjin Medical Co., Ltd. #1022 Sicox Tower, 513-14, Sangdaewon-Dong, Chungwon-Ku, Sungnam-Si, Kyunggi-Do, Republic of Korea

Device Identification

Trade Name:	i-Scope 200
Common Name:	Digital Stethoscope
Classification Name:	Stethoscope per 21 CFR § 870.1875
Product Code:	DQD

Substantially Equivalent Predicate Legally Marketed Devices

The subject device, i-Scope 200, is substantially equivalent in technical characteristics and intended used to:

- 3M Littmann Electronic stethoscope, Model 4000(K003723)
- JABES electronic stethoscope(K031446)

Device Description

i-scope 200 digital stethoscope is a new advanced product compared to conventional stethoscopes that removes noise from tube of standard stethoscope. It dose not cause pain to the ear despite long-term use due to newly introduced soft materials applied in earphone. i-scope 200 digital stethoscope is intended for

medical diagnostic purposes only. It is used for the amplification of heart, lung and other body sounds with selective frequency filtering. This product is not designed, sold, or intended for any other use.

Indications for Use

The i-Scope 200 is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

Comparison to leally marketed predicate devices

The i-Scope has the same intended use and similar technological characteristics as the predicate devices. Thus, the i-Scope 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

DEC - 6 2006

Dongjin Medical Co., Ltd.
c/o Min-Kang Kim
Manager
#1022 Sicox Tower, 513-514
Sangdaewon-Dong, Chungwon-Ku
Sungnam-Si, Kyunggi-Do
REPUBLIC OF KOREA 462-806

Re: K062364
Trade Name: I-Scope 200
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: II (two)
Product Code: DQD
Dated: October 11, 2006
Received: October 11, 2006

Dear Mr. Kim:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K062364

Device Name: i-Scope 200

Indications for Use:

The i-Scope 200 is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062364

Prescription Use ___√___ 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)