MAY 0 2 2002

K020471

510(K) SUMMARY

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:	AViTA International Corp
	Address:	9F, No. 78, Sec. 1, Kwang-Fu Rd., San-Chung, Taipei County, Taiwan, R.O.C.
	Phone:	001-886-2-85121568
	Fax:	001-886-2-85121347
	Contact:	Mr. Geo Lin, General Manager
2.0	Device Name:	**AViTA TS0/TS1 Infrared Ear Thermometer** Models TS-001,TS-002,TS-003 and TS-101,TS-102,TS-103
3.0	Classification:	Class II
4.0	Predicate Device:	1. Braun ThermoScan IRT 3020 One Seconds Ear Thermometer (K983295) 2. K-Jump Health Co., Ltd.'s Infrared Ear Thermometer, Model KI-8120 (K984551)
5.0	Device Description:	**AViTA TS0/TS1 Infrared Ear Thermometer** is a hand-held, non-sterile, reusable clinical thermometer intended for the determination of human temperature by radiation emitted via the human ear **(Tympanic Temperature).**
6.0	Intended Use:	The **AViTA TS0/TS1 Infrared Ear Thermometer** is intended for the intermittent measurement and monitoring of human body temperature, through the opening of auditory canal, by consumers in the home.
7.0	Performance Summary:	In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ASTM E1965-98, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **AViTA TS0/TS1 Infrared Ear Thermometer** have the same intended use and similar technological characteristics as the Braun ThermoScan IRT 3020 One Seconds Ear Thermometer (K983295) and K-Jump Health Co., Ltd.'s Infrared Ear Thermometer, Model KI-8120 (K984551). Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **AViTA TS0/TS1 Infrared Ear Thermometer**, Models TS-001,TS-002,TS-003 and TS-101,TS-102,TS-103 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

MAY 02 2002

Mr. Ke-Min Jen
Official Correspondent
Hivox Biotek, Incorporated
12 F, No. 156, Chien Kuo
North Road
Taipei,
CHINA (TAIWAN)

Re: K020471
Trade/Device Name: HIVOX Cover-Free Ear Thermometer TS-510
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer (IR Ear)
Regulatory Class: II
Product Code: FLL
Dated: February 6, 2002
Received: February 12, 2002

Dear Mr. Jen:

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) 594-4618 . 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

To: Ear Mtr. Durone

HIVOX BIOTEK INC.

12F, No. 156, Sec. 1 Chien Kuo N. Rd., Taipei 104, Taiwan, ROC
TEL: 886-2-2516-8488 FAX: 886-2-2516-6995
E-MAIL: hivox@ms58.hinet.net

510 (K) NUMBER (IF KNOW): **K020471**

DEVICE NAME: HIVOX Cover-Free EAR THERMOMETER TS-510

INDICATIONS FOR USE:

The device is an electronic clinical thermometer using an infrared thermopile sensor to detect body temperature of the radiation from the tympanic part of the human of all ages at home.

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

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 Dental, Infection Control,
and General Hospital Devices
(510(k) Number K020471

J-