SEP 1 0 2001

510(K) SUMMARY

K012136

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

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Contact: Mr. Geo Lin, General Manager

2.0 Device Name: **AViTA Agil IT101 Instant Digital Thermometer**

3.0 Classification: Class II

4.0 Predicate Device: Microlife IT2CA1 Digital 4-Sec. Predicative Thermometer (K990168)

5.0 Device Description: AViTA Agil IT101 Instant Digital Thermometer is a hand-held, non-sterile, reusable clinical thermometer and is designed to instantly take the body temperature orally, rectually or under the arm. With its rapidity and precisemenss, Agil IT101 gives a temperature reading in merely 4 seconds orally and 6 seconds rectally and under the arm respectively.

6.0 Intended Use: The **AViTA Agil IT101 Instant Digital Thermometer** is intended for the intermittent measurement and monitoring of human body temperature, in either Rapid mode (4-seconds orally, 6-seconds rectally and under the arm -- Predicative Temperature), or standard mode(actual determination of temperature), orally, rectally and under the arm , 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 E1112-98, PrEN 12470-3, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **AViTA Agil 1T101 Instant Digital Thermometer** have the same intended use and similar technological characteristics as the Microlife IT2CA1 Digital 4-Sec. Predicative Thermometer (K990168). 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 Agil 1T101 Instant Digital Thermometer**, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

AViTA International Corporation
Mr. Allen Reich
Harvest Consulting Corporation
900 North Switzer Canyon Drive, #142
Flaggstaff, Arizona 86001

Re: K012136
Trade/Device Name: AViTA Agil IT101 Instant Digital Thermometer
Regulation Number: 880.2910
Regulation Name: Thermometer, Electronicthermometer, Predictive Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 10, 2001
Received: July 9, 2001

Dear Mr. Reich:

This letter corrects our substantially equivalent letter of September 10, 2001 regarding the trade name.

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). 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 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 continue 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 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (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

510 (k) NUMBER (IF KNOWN): K012136

DEVICE NAME: **AViTA Agil IT101 Instant Digital Thermometer**
AViTA International Corp.

INDICATIONS FOR USE:

AViTA Agil IT101 Instant Digital Thermometer is used for the intermittent measurement and monitoring of human body temperature , orally, rectally and under the arm, by consumers in the home.

AviTA Agil IT101 Instant Digital Thermometer is a hand-held, non-sterile, reusable clinical thermometer intended for the determination of human temperature in either rapid mode (4-seconds orally, 6-seconds rectally and under the arm -- Predicative Temperature), or standard mode(actual determination of temperature),

The device is to used and installed by people exception of handicapped persons and children.

The device is to used in the ENVIRONMENT of room temperature & normal environment condition.

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

Concurrence of CDRH, Office of Device Evaluation

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012136