JUN 17 2005

P 1/2

XVI. PREMARKET NOTIFICATION [510(K)] SUMMARY – K050156

Applicant name:

IYIA Technologies, Inc.
870 Rancheros Drive
San Marcos, CA 92069
(760) 432-8285
(760) 432-8286 (fax)

Contact Person: Mr. Adrian Pelkus, President
Date Summary Prepared: May 27, 2005

Device Name:

Trade Name:	WHS-1000 Wound Treatment System
Common Name:	Misty™
Classification Name:	Hyperbaric Oxygen Chamber for Extremities
Classification No.:	878.5650

Claiming Substantial Equivalence To:

VX-400 Topical Hyperbaric Oxygen Chamber, Vascular One, Inc., K022028.

Device Description

The Wound Treatment System is composed of a rectangular, rigid plastic shell that is of sufficient size to accommodate the patient's foot. There are four fittings on the chamber: one for oxygen tubing that fills the chamber, one for a pressure sensor, one to allow the mist to enter the chamber and one for water transfer. The front panel control consists of a plastic panel with switches, indicators and timer controls; these connect to the Wound Treatment System via a cable. The system plugs into an AC wall outlet.

The Product and Its Intended Use

The Misty™ Wound Treatment System provides humidified hyperbaric oxygen to open, chronic wounds as an adjunct therapy in wound management and treatment. In addition, the device can also provide heat, gentle massage, moisture, and infrared and ultraviolet light therapy.

The device is intended for the treatment of the following kinds of wounds:

- skin ulcerations due to diabetes, venous stasis, and post surgical infections
- gangrenous lesions,

- decubitus ulcers
- amputations/infected stumps
- skin grafts
- burns
- frostbite

Caution: Federal law restricts this device to use by or on the order of a physician or podiatrist.

Summary of Technological Characteristics

The Misty™ Wound Treatment System WHS-1000 has the same technological characteristics as its predicate devices.

Nonclinical Testing: The physical properties of the materials used to manufacture the IYIA Wound Treatment System are tested by the suppliers to ensure they meet the specifications for the finished device. The testing standards are established by ASTM. The materials that come in contact with the body are also tested using ISO methods for biocompatibility. All of the materials meet the specifications for the device, as certified by the supplier of the materials to IYIA Technologies, Inc.

Performance Data: N/A

Clinical Data: N/A

-- END OF 510(k) SUMMARY --

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2005

IYIA Technologies Incorporated
C/o Mr. Alan Donald, MS, MBA, RAC
Matrix Medical Consulting Incorporated
11440 West Bernardo Court, Suite 380
San Diego, California 92127-1644

Re: K050156
Trade/Device Name: WHS-1000 Wound Treatment System
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical oxygen chamber for extremities
Regulatory Class: III
Product Code: KPJ
Dated: April 26, 2005
Received: April 27, 2005

Dear Mr. Donald:

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) 276-0115 . 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
(As required by ODE for all 510(k)'s received after 1/2/96.)

510(k) Number: K050156

Device Name: Misty™ Wound Treatment System

Indications for Use:

The Misty™ Wound Treatment System provides humidified hyperbaric oxygen to open, chronic wounds as an adjunct therapy in wound management and treatment. In addition, the device can also provide heat, gentle massage, moisture, and infrared and ultraviolet light therapy.

The device is intended for the treatment of the following kinds of wounds:

- skin ulcerations due to diabetes, venous stasis, and post surgical infections
- gangrenous lesions,
- decubitus ulcers
- amputations/infected stumps
- skin grafts
- burns
- frostbite

Caution: Federal law restricts this device to use by or on the order of a physician or podiatrist.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative
and Neurological Devices

510(k) Number K050156