AUG 24

K990037

SECTION 5. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Name, Address, Phone and Fax number of the Applicant:
American Immuno Tech
320 Kalmus Drive
Costa Mesa, CA 92626
Phone: 714-241-8431
Fax: 714-241-8435

Contact Person: Alan Davidner

Date Prepared: January 5, 1999

Device Name: Neptune Waste Management System

Device Description: The Neptune Waste Management System (hereafter referred to as the Neptune System) collects and evacuates surgical fluid waste as well as smoke generated from lasers and electro-cautery devices. The Neptune System also provides its own independent suction capability, in lieu of wall suction, and can electronically measure fluid volume output. The Neptune System is a closed system. It replaces vacuum canisters and reduces the solid waste that is generated by the use of suction canisters.

The Neptune System includes two pieces of equipment: a Rover unit and the Docking Station. The Rover has an accessory, the Infrared Transmitter, to actuate the Rover's smoke evacuation capability.

The Rover incorporates a 20 liter basin for the collection of fluid waste and can evacuate smoke generated from electro-cautery and laser devices through a variety of disposable tubing kits. The Rover's basin features volume markings and a built-in electronic volume meter. The Rover's manifold can handle up to four suction lines. The Rover features a vacuum blower motor that is used to evacuate smoke. The vacuum blower motor can also be used as an independent source of suction.

The Docking Station's control panel incorporates three switches that allow for simple user interaction and control of the process. A series of voice alarms provides user instructions for ease of use.

The Infrared Transmitter attaches onto the power cord of a laser or an electro-cautery device. When a laser or electro-cautery device is turned on, an infrared signal is sent that activates the Rover's smoke evacuation capability.

Intended Use: The Neptune Waste Management System is intended to be used in the Operating Room, Pathology, Surgical Centers and Doctor's Offices to collect and sterilize surgical fluid waste as well as evacuate smoke generated from electro-cautery or laser devices.

Substantial Equivalence: The Neptune Waste Management System is substantially equivalent in materials, design and intended use to a combination of the following 510(k) devices and 510(k) exempt devices: The Steris® SafeCycle 40, a fluid waste management system; the Niche Medical SmartVac™, a smoke evacuation system; the Dornoch Red>Away, an infectious fluid collection and disposal system; and the Stackhouse Biovac Laser Fume Evacuation System (K874512).

Performance testing: Testing was conducted on the Neptune Waste Management System to verify the ability of the Neptune Waste Management System to sterilize fluid medical waste, to verify the ability of the manifold inlet port valves to prevent reflux and to verify battery back-up and recharge.

Software Testing: Verification and validation testing was performed on the device software.

Electrical Safety Testing: The device design will be compliant with IEC 601.1 and UL 2601.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 1999

Ms. Esther Saltz
American Immuno Tech
320 Kalmus Drive
Costa Mesa, California 92626

Re: K990037
Trade Name: Neptune Waste Management System
Regulatory Class: II
Product Code: FYD
Dated: May 24, 1999
Received: May 26, 1999

Dear Ms. Saltz

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K990037

Device Name: Neptune Waste Management System

Indications For Use: The Neptune Waste Management System is intended to be used in the Operating Room, Pathology, Surgical Centers and Doctor's Offices to collect and sterilize surgical fluid waste as well as collect smoke generated from electro-cautery or laser devices.

(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 Dental, Infection Control, and General Hospital Devices
510(k) Number K990037

Prescription Use ____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)

(Optional Format 1-2-96)