NOVA HEALTH SYSTEMS
PRODUCT SPECIFICATIONS

Description
(length x width x heigth)

7x7x7 inch hood with bottom
7x7x7 inch hood with NO Bottom

10x10x10 inch hood with bottom
10x10x10 inch hood with NO Bottom

12x12x12 inch hood with bottom
12x12x12 inch hood with NO Bottom

18x18x18 inch hood with bottom

24x24x24 inch hood with bottom

12x12x10 inch hood with bottom

10x10x8 inch hood with bottom
10x10x8 inch hood with NO Bottom

8.5x8.5x8.5 inch hood with bottom
8.5x8.5x8.5 inch hood with NO Bottom

10x16x5 inch tent

11x18.5x7 inch tent

Specifications: Zinc Metal Collar to cover frame ends. App. 2.5" long
Zinc Metal Frame app. 0.1" dia.
PVC Vinyl - clear 3.5 mil thick.
Blue Holes 22mm (1") opening on body and back
NOTE: See actual product samples for exact materials used

REGISTRATION NO.: 2246737
FOR: 2005

OWNER / OPERATOR NO.: 2246737

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT

NOTE: This form is authorized by Section 510 of the Cosmetic Act (21 U.S.C. 360). Failure to report this violation of Section 301(p) of the Act (21 U.S.C. 331(violate this provision may, if convicted, be sut imprisonment or both. The submission of any repor misleading in any material respect is a violation of Sec U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 10

REGISTERED ESTABLISHMENT

NOVA HEALTH SYSTEMS, INC.
1001 BROAD ST., 3RD FLR.
UTICA, NY 13501

OWNER / OPERATOR

NOVA HEALTH SYSTEMS, INC.
1001 BROAD ST., 3RD FLR.
UTICA, NY 13501

OFFICIAL CORRESPONDENT

MR. WADE ABRAHAM
NOVA HEALTH SYSTEMS, INC.
P O BOX 4335
UTICA, NY 13504-4335

ESTABLISHMENT TYPE MANUFACTUR
INITIAL DISTRIB

Detach Part 1 and Keep as Proof of Registration.
Complete and Return Part 2.
Detach and Refer to Part 3 for Specific Instructions.

Form FDA 2891e (5/02) **Part 1 - Keep for Your Records** Form Approved: OMB Expiration Date: Mar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 21 1989

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Nova Health Systems, Inc.
Attn: Robert E. Delano
409 VPR Commerce Center
Blackwood, New Jersey 08012

Re: K893713
Oxygen Tent
Dated: May 12, 1989
Received: May 18, 1989
Regulatory Class: I

Dear Mr. Delano:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

George C Murray

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology,
and Radiology Devices
Office of Device Evaluation
Center for Devices and
Radiological Health