K970352

510(k) Summary

Niche Medical SmartVac Smoke Evacuation System

NOV - 4 1997

1. Sponsor/Applicant Name, Address

Niche Medical Inc.
55 Access Road, Suite 900
Warwick, RI 02886

Contact Person/Telephone Number:

Dennis Sleister, President
Tel: (401) 732-3321

Date of Summary Preparation:

January 29, 1997

2. Device Name

Trade/Proprietary Name:	SmartVac Smoke Evacuation System
Common/Usual Name:	Smoke/plume Evacuation System
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories Laser Surgical Instrument for Use in General and Plastic Surgery and Dermatology and Accessories.

3. Identification of the predicate or legally marketed device(s) to which equivalence is being claimed

Niche Medical ECS.01 Plume Evacuation Containment System

4. Device Description

The SmartVac operates by collecting air containing smoke/plume from the site of origin, filtering the biological and chemical components, and returning the filtered, odor-free air to the room.

The SmartVac functions by creating a partial vacuum, near the smoke source, which pulls the smoke into a collection accessory and through a filtration system. After filtration, the air moves through the motor/blower and exits the cabinet.

The major components of the SmartVac are:

1) collection devices which consist of plain tubing or tubing with a procedure specific Collection Tip on the distal end;

2) a filtration system which includes a First Filter which is a combination High Efficiency Particulate (HEPA) and carbon filter intended for limited, multiprocedure usage;

3) a second Filter which is a large Ultra Low Penetration Air (ULPA) filter;

4) a pressure sensor monitors the pressure differential across the filter and activates the Change ULPA light when a filter nears occlusion; and

5) a vacuum system which consists of a motor/blower designed to pull a partial vacuum in the Filtration System and its various controls.

In use, the distal end of the Collection Accessory is positioned close to the surgical site. When electrocautery or laser usage produces smoke, the user activates the SmartVac. Air, pulled from in front of the Collection Tip or end of the Tubing, flows through the First Filter which removes most biological particulates and noxious gases. It then passes through the Second Filter for ULPA filtration before it goes through the motor/blower and exits the rear of the cabinet. Pressure sensors monitor the pressure differential across both filters. Those monitoring the First Filter control the three lights of the Filter Status Indicator ULPA light. The sensors on the First Filter also sense any sudden increase in pressure from invagination of either tissue or a foreign object.

The Collection Accessories offered in the SmartVac Evacuation System include corrugated tubing, electrosurgical shrouds, smaller tubing and/or connectors, laser resistant wands, replacement filters and a remote switch.

5. Intended Use

The SmartVac is intended to be used for the evacuation of plume from the use of electrocautery, laser or other plume producing devices. It is intended to be used during both open surgery or endoscopic surgical procedures performed in the operating room or procedure room of hospitals, ambulatory surgery centers, clinics or in a physician's office.

6. A statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device(s) cited

The SmartVac system has several technological characteristics that are superior to the ECS.01 including a higher flow motor/blower, lower operating sound level a high flow system ULPA filter, a physically smaller filter canister with more carbon, an electronic rather than mechanical pressure sensing system to determine when the system should shut-off, more rapid pressure relief and an automatic compensation for a change in tubing size. The SmartVac uses two filters whereas the ECS.01 uses one filter.

The SmartVac offers a flexible support to hold Collection Tubing in place. This minimizes the need to have a person hold it close to the surgical site. The support can be draped in a sterile sleeve. In comparison, the user has to hold the ECS.01 system during use.

7. For 510(k)s where determination of equivalence is based on performance data

Performance testing demonstrated that the SmartVac has flow rates and absorption capacity greater than that of the ECS.01.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Niche Medical Inc.
c/o Cynthia J.M. Nolte, Ph.D.
Associate Regulatory Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

NOV - 4 1997

Re: K970352
Trade Name: SmartVac Smoke Evacuation System
Regulatory Class: II
Product Code: FYD
Dated: August 15, 1997
Received: August 18, 1997

Dear Dr. Nolte:

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 current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970352

Device Name: SmartVac Smoke Evacuation System

Indications For Use:

The SmartVac Smoke Evacuation System is indicated for the evacuation of plume from electrocautery, laser or other plume generating devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970352

(Optional Format 1-2-96)