

JUN 29 1998

K980915

VALLEYLAB OPTIMUM™ SMOKE EVACUATOR SYSTEM SUMMARY OF SAFETY AND EFFECTIVENESS

I. Product description:

The Valleylab OptiMumm™ Smoke Evacuator system includes the OptiMumm™ smoke evacuator unit, footswitch, fluid canister ring, fluid canister kit, tubing sets, filters, adapters, remote activation unit (RapidVac™ Electrosurgery Sensor), and smoke evacuator wand. A centrifugal fan provides suction, drawing the smoke into and through the system and filters. The smoke evacuator unit is designed to provide an airflow (suction) of 2.70 cfm minimum to 20.0 cfm maximum with the 7/8" tubing set. The dimensions of the evacuator are 17"D x 13-3/8"W x 9"H (without feet) and it weighs approximately 34 lbs. (without filters).

The smoke evacuator is to be used with a variety of accessories including a wand, tubing, adapters, filters, and fluid canister. These accessories will be offered both sterile and non-sterile and will be sold under separate catalog numbers.

All of the controls for the smoke evacuator unit are located on the front panel. These are:

- Mode Selector - A dial control for the unit operation with four mode settings:
 - Standby - powers up the unit without activating the motor or vacuum flow.
 - Footswitch - used to turn the smoke evacuator on or off with the optional footswitch.
 - Remote Flow Control (RapidVac) - used to control the vacuum flow simultaneously with activation of a Valleylab electrosurgical pencil. The mode is controlled with the optional generator Interlink or electrosurgery sensor.
 - Continuous - used to operate the evacuator using continuous air flow.
- Variable Speed Selector - This dial controls five variable speed settings. The user set speed setting is indicated by LED's.
- Pressure Sensor Test and Status Light Indicator - A button is pressed to test pressure drop across an UHPA filter. The filter status is indicated by two LED's: green (good filter), red (replace filter), and , flashing red (filter not installed).
- RapidVac Connect - Accepts the cord for the remote flow control via the current monitor.
- Footswitch Connect - Accepts one pneumatic footswitch.

The rear panel of the smoke evacuator incorporates the AC line receptacle, which fits a detachable line cord and contains a locking mechanism, the RapidVac connect which accepts the cord for remote flow

control by way of the ECG blanking output of certain Valleylab generators, and, a circuit breaker. A handle is also included on the rear of the unit for carrying purposes

The OptiMumm™ Smoke Evacuator system requires the use of two filters; an ULPA filter and a disposable prefilter. The ULPA filter is a two stage filter the first stage of which is a charcoal media and the second stage, the ULPA filter. The ULPA is 99.999% efficient at 0.12 microns and will have an estimated useful life of approximately 25 hours. It is designed to trap microscopic particles and absorb odors generated by electrosurgical procedures. The disposable prefilter is a single use 0.3 micron filter and is designed to trap gross particulate matter. Its useful life is approximately 30 minutes of continuous use with heavy smoke.

Surgical smoke is collected at the surgical site by tubing or a wand which is attached by tubing to the smoke evacuator unit. It can also be collected by the Valleylab Accuvac smoke attachment which clips to the Valleylab electrosurgical pencil. Activation of the smoke evacuator unit can be controlled through a footswitch, or the unit can be placed in a continuous flow mode, or it can be activated via the remote sensor, the Valleylab RapidVac.

The remote flow control unit, RapidVac, allows flow control of the smoke evacuator unit on activation of the electrosurgical pencil (active). The unit is basically a current sensor through which the cord of the electrosurgical pencil is inserted. When the pencil is keyed (activated), the sensor detects current flow through the pencil cord and activates the smoke evacuator so that the operating speed increases to the speed pre-selected by the user. When the pencil is deactivated, the smoke evacuator reduces flow to a low flow purging setting.

Intended Use:

The Valleylab OptiMumm™ Smoke Evacuator and its accessories are designed to evacuate surgical smoke and incidental fluids from electrosurgery or laser surgery sites improving visibility at the site and removing potential health hazards associated with surgical smoke. The system will be used in surgical settings in the hospital, surgical centers, or in physicians offices.

III. Safety and Performance Data

Safety and performance of the Valleylab OptiMumm™ Smoke Evacuator and its accessories have been evaluated and verified through validation/verification and bench testing. The smoke evacuator unit is designed to conform to the following standards:

UL2601 Medical Electrical Equipment, Part 1: General requirements for Safety

EN55011 - Specification for Limits/methods of measurement of radio disturbance characteristics of industrial, scientific and medical radio frequency Equipment

Product testing showed conformance to design specifications and also to the above standards.

The biological safety of the Valleylab OptiMumm™ Smoke Evacuator tubing sets, adapters and wands has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The materials have been tested in accordance with USP Class III minimum and ISO Standard 10993-1, Biological Evaluation of Medical Devices, Part 1, where applicable.

IV. Summary of Substantial Equivalence

The Valleylab OptiMumm™ smoke evacuator system is substantially equivalent in function and intended use to the following legally marketed devices manufactured by Stackhouse, Inc., 1100 Bird Center Drive, Palm Springs, California 92262:

Stackhouse Point One Surgical Smoke Evacuator
Stackhouse MiniVac Surgical Smoke Evacuator

Their intended purpose is to remove electrosurgical/laser smoke from the surgical site.

The Point One smoke evacuator received FDA concurrence under accession number K874512 on 1/27/88 and the MiniVac received FDA concurrence under accession # K912651 on 7/8/91.

Both of the above Stackhouse smoke evacuators and the Valleylab OptiMumm™ smoke evacuator are similar in dimensional characteristics and have the same ULPA filters/efficiencies. The suction flow for these devices are substantially the same as are the accessories which are used with each of the units. The Valleylab OptiMumm™ smoke evacuator can be activated through use of a remote sensing unit. The Stackhouse Point One and MiniVac smoke evacuators do not contain remote sensing capabilities.

The use of the Valleylab OptiMumm™ smoke evacuator system for the removal of surgical smoke is substantially equivalent to the uses of the Stackhouse smoke evacuators noted above which have been cleared by FDA in previous 510(k) submissions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1998

Mr. Peter D. Geary
Senior Engineer
Valleylab®, Incorporated
5920 Longbow Drive
Boulder, Colorado 80301-3299 USA

Re: K980915
Trade Name: Valleylab OptiMumm™ Smoke Evacuator System
Regulatory Class: II
Product Code: FYD
Dated: June 9, 1998
Received: June 12, 1998

Dear Mr. Geary:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

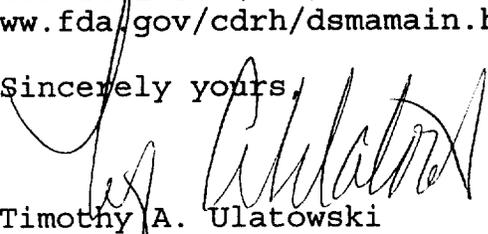
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Indications For Use

510(k) Number (if known): K980915

Device Name: Valleylab OptiMumm™ Smoke Evacuator System

Indications For Use:

The Indications for Use of the Valleylab OptiMumm™ Smoke Evacuator system are for the removal of smoke and incidental fluids produced during electrosurgery and/or laser surgery. The removal of smoke from the surgical site improves visibility and reduces potential health hazards associated with surgical smoke.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 2.1 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Chin S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980915