K001082 JUN 15 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturing Site:	Stackhouse Incorporated 1100 Bird Center Drive Palm Springs, CA 92262
Contact:	Tom Gutierrez (760) 778-7255 (phone) (760) 778-7274 (fax)
Summary Date	February 15, 2000
Device Trade Name:	Stackhouse Smoke Evacuator ST-3000 (115VAC) and ST-3100 (230VAC)
Device Common Name	Common Name: Smoke Evacuator
Device Classification Name:	Classification name: Air-handling apparatus for a surgical operating room. Regulation 21CFR878.5070
Establishment Registration Number	2020276
Device Class:	Class II
Classification Panel:	General and Plastic Surgery
Predicate Device:	The predicate devices are the Stackhouse AireSafe MiniVac Surgical Smoke Evacuator (K912651) and the Valleylab OptiMumm Smoke Evacuator (K980915).
Device Description:	The Stackhouse Smoke Evacuator ST-3000/ST-3100 is an apparatus used for removing smoke from surgical sites.
Intended Use:	The Stackhouse Smoke Evacuator ST-3000/ST-3100 is intended to be used to evacuate the smoke created by electrosurgery, laser surgery, or power tool surgical procedures. Locations for use include Operating Rooms, Trauma, Endoscopy and Laparoscopy Sites
Substantial Equivalence	The Stackhouse Smoke Evacuator ST-3000 and ST-3100 is substantially equivalent to Stackhouse AireSafe MiniVac Surgical Smoke Evacuator (K912651) and the Valleylab OptiMumm Smoke (K980915) in that: - The intended use is the same - The performance attributes are similar
Summary of Testing and Validation:	The material used in the Stackhouse Smoke Evacuator ST-3000 and ST (115VAC) and ST-3100 (230VAC) were tested in accordance to industry recognized test standards and was validated for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2000

Tom Gutierrez P.E.
Regulatory Compliance Engineer
Stackhouse, Incorporated
1100 Bird Center Drive
Palm Springs, California 92262-8099

Re: K001082
Trade Name: Stackhouse Smoke Evacuator, Models ST-3000, ST-3100
Regulatory Class: II
Product Code: FYD
Dated: February 4, 2000
Received: April 4, 2000

Dear Mr. Gutierrez:

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,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510 (k) Number (if known): K 001082

Device Name: Stackhouse Smoke Evacuator ST-3000 (115VAC) and ST-3100 (230VAC)

Indication For Use:

The Stackhouse Smoke Evacuator ST-3000 (115VAC) and ST-3100 (230VAC) is intended to evacuate the smoke created by electrosurgery, laser surgery, or power tool surgical procedures. Locations for use include Operating Rooms, Trauma, Endoscopy and Laparoscopy Sites.

(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 K001082

Prescription Use _____ OR Over-The-Counter Use

(Per 21 cfr 801.109)

(Optional Format 1-2-96)