K121675

Synergetics™

JUN 21 2012

Synergetics VersaVit

Section 5

510 (k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

Applicant's Name and Address:	Synergetics 3845 Corporate Centre Drive O'Fallon, MO 63368
Contact Person:	Dan Regan, RA Director (T) 636-794-5013 (F) 636-939-6885
Date Prepared:	June 21, 2012
Device Trade Name:	VersaVit
Common Name:	Vitreous Aspiration and Cutting
Regulation Number:	21 CFR 886.4150
Regulation Name:	Vitreous Aspiration and Cutting Instrument
Regulatory Class:	Class II
Product Code:	HQE
FDA Panel:	Ophthalmic
Predicate Device:	Alcon Accurus, K911808
Device Description Summary:	The VersaVit is a compact, stand-alone, portable device with a pneumatic vitrector drive, aspiration, and illumination through an imbedded solid state LED light source.
Indications for Use:	The Synergetics VersaVit is an ophthalmic microsurgical system that is indicated for posterior segment (i.e. vitreoretinal) ophthalmic surgery. The integrated light

source is intended to illuminate the eye during vitreoretinal procedures.

Summary of Technological characteristics: The Synergetics VersaVit is equivalent to the predicate device, the Alcon Accurus in terms of its intended use, technological characteristics, energy used, materials, and FDA-recognized standards used for performance testing.

The subject device includes 1) a console for controlling the functions and for powering the device; 2) consumable convenience packs, which include fluid aspiration drainage bags; and 3) a control accessory (foot pedal).

A comparison matrix is included below.

Summary of Non-clinical tests: The VersaVit has undergone testing and is in compliance with the applicable requirements of safety standards. The subject device was found to perform equivalently to the predicate device in a series of bench tests. Therefore, the subject device and the predicate device have similar safety, effectiveness, and performance profiles.

Substantial Equivalence Basis: The conclusions performed by independent laboratories and internal comparative bench testing provide objective evidence to substantiate the Synergetics VersaVit is as safe and effective as the predicate device, the Alcon Accurus.

Synergetics™

Synergetics VersaVit

Section 5

510 (k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

Comparison of Technical Characteristics		
Element	**Synergetics VersaVit (Subject Device)**	**Alcon Accurus (Predicate Device K911808)**
Intended Use	Posterior Segment Vitrectomies	Anterior and Posterior Segment Ophthalmic Surgery
Microprocessor based	Yes	Yes
Aspiration Pump Type	Diaphragm	Venturi
Operating Pressure	72.5 – 120 PSI	70 – 120 PSI
Pneumatic Source	Compressed Air CO_2 cartridges	Compressed Air
Unit Height x Weight x Depth	10" x 13" x 11"	20" x 19" x 20.5"
Unit weight	25 pounds	90 pounds
Electrical power specifications	100-120V 220-240V 50/60 Hz	100-120V 220-240V 50/60 Hz
Consumable Packs provided sterile	Yes	Yes
Consumable Packs method of sterilization	ETO	ETO

Synergetics™

Synergetics VersaVit

Section 5

510 (k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

Comparison of Technical Characteristics		
Element	**Synergetics VersaVit (Subject Device)**	**Alcon Accurus (Predicate Device K911808)**
Consumable Packs Sterility Assurance Level	10^{-6}	10^{-6}

Quality Management System:

Synergetics is an ISO 13485 compliant company and is required to ensure our quality management system and design control practices fully comply with internal quality system standards and domestic regulations. Pursuant to our design control process, Synergetics has established a risk management process that ensures during the design validation phase, the safety and effectiveness of the device meets applicable input requirements and complies with applicable harmonized standards.

Risk Management:

Risk Management has been implemented and complies with ISO 14971, Medical Devices – Application of Risk Management to Medical Devices and GHTF/SGS/N15R8, Implementation of Risk Management Principles and Activities within a Quality Management System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 2 1 2012

Synergetics
c/o Mr. Ned Devine
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062

Re: K121675
Trade Name: VersaVit
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous aspiration and cutting instrument
Regulatory Class: Class II
Product Code: HQE
Dated: June 5, 2012
Received: June 6, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121675

Device Name: Synergetics VersaVit

Indications For Use:

The Synergetics VersaVit is an ophthalmic microsurgical system that is indicated for posterior segment (i.e. vitreoretinal) ophthalmic surgery. The integrated light source is intended to illuminate the eye during vitreoretinal procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121675