MAY 3 0 2012

K120170

VISIONCARE DEVICES

1246 Redwood Blvd.
Redding, California 96001
(530) 243-5047

5 510(K) Summary

5.1 Date Prepared:	1/13/2012
5.2 510(K) Submission Type:	This is a traditional 510(K)
5.3 Submitter/Owner:	**VisionCare Devices, Inc.** FDA #2939964 1246 Redwood Boulevard Redding, California 96003 +1-530-243-5047 Phone +1-530-241-7532 Fax
5.4 Key Contacts:	**Kurtis Montegna** Regulatory Affairs Manager Kurtis@VitCutter.com **Susan Cook** General Manger Susan@VitCutter.com
5.5 Trade Name	ProCare Plus™ Vitrectomy System
5.6 Common Name	Vitrectomy System
5.7 Classification Name:	886.4150 Vitreous Aspiration and cutting instrument. Product Codes (HQE)
5.8 Predicate Devices	K980480 – Syntec Vitman – HQC (**Primary Predicate Device**) K904909 – YPR 2001 – HQE **(Secondary Predicate Device)** K896622 – Intrector – HKP **(Secondary Predicate Device)**

5.9 Device Description

The ProCare Plus™ Vitrectomy System is a portable surgical system intended for use in both anterior and posterior segment (vitrectomy) ophthalmic surgeries.

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5.10 System Power	The ProCare Plus™ Vitrectomy System is an AC powered device with an internal Li-Ion battery that provides backup power in the event that AC power is interrupted.
5.11 System Control	The system is primarily run from one multifunction footswitch which gives the surgeon control over all of the surgical functions.
5.12 System Functions	The ProCare Plus Vitrectomy system provides many of the functions required by the ophthalmic surgeon for performing a vitrectomy including vitreous cutting and aspiration, illumination, and fluid-air exchange.
5.13 Intended Use:	The ProCare Plus™ Vitrectomy System is a portable surgical system intended for use in both anterior and posterior segment (vitrectomy) ophthalmic surgeries.
5.14 Indications for Use: • Identical to predicate devices	The PROCARE PLUS™ Vitrectomy System is indicated for use in support of the following ophthalmic surgical procedures: Removal of vitreous in cases of vitreous clouding, diabetic vitreal hemorrhaging, trauma, including contusions, penetrations, and intraocular foreign bodies; opacity, inflammation, endophthalmitis (bacterial or fungal), uvitis • Removal of lens fragments after cataract surgery; • Remove vitreous traction under the retina producing localized or complete retinal detachment; • Removal of samples of vitreous for diagnostic purposes, i.e. endophthalmitis; • Treatment of vitreous loss during cataract surgery; • Clean vitreous strands from the cataract wound; • Provide internal illumination for vitreous surgery; Provide air pressure for maintaining intraocular pressure for retinal surgery.

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Table 1- Predicate Device Comparison Table

	Current Submission	Primary Predicate	Secondary Predicates	
	ProCare Plus	**Vitman**	**YPR 2001**	**Intrector**
510(K) Number		K980480	K904909	K896622
Intended Use	Anterior/Posterior Ophthalmic Surgery	Anterior/Posterior Ophthalmic Surgery	Anterior/Posterior Ophthalmic Surgery	Anterior/Posterior Ophthalmic Surgery
Computer Based System	No	No	No	No
Vitrectomy				
Type:	Guillotine	Guillotine	Guillotine	Guillotine
Drive Mechanism:	Pneumatic	Pneumatic	Pneumatic	Pneumatic
Maximum Cut Rate:	3000 cuts/minute	2000 cuts/minute	1200 cuts/minute	1200 cuts/minute
Irrigation/Aspiration	Yes	Yes	Yes	Yes
Aspiration Type	Electrical	Venturi	Venturi	Syringe
Linear Control:	Yes	Yes	Yes	Yes
Maximum Vacuum:	400 mmHg	400 mmHg	400 mmHg	Unknown
Phacofragmentation	No	Yes	No	No
Diathermy	No	No	No	No
Fiber Optic Light Source	Yes	Yes	Yes	No
Dual/single output:	Single	Dual	Single	NA
Lamp Type:	HB LED	Halogen	Halogen	NA
Air Infusion	Yes	Yes	Yes	No
Maximum Pressure:	95 mmHg	95 mmHg	95 mmHg	NA
Multifunction Footswitch	Yes	Yes	Yes	No
Power				
AC Power:	Yes	Yes	Yes	Yes
Battery:	Yes	Yes	No	Yes

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5.15 Substantial Equivalence Summary – Differences		
Predicate Device(s)	**ProCare Plus Vitrectomy System difference**	**Summary**
Venturi Vacuum Syringe Vacuum	**On-board vacuum pump**	The on-board vacuum pump produces the same vacuum characteristics and pressures as both the venturi and manual syringe vacuum systems. The vacuum pump is substantially equivalent to the predicate device.
Halogen Lamps	**LED**	Halogen lamps have been replaced with a LED lamp that significantly reduces heat and significantly reduces "Blue Light Toxicity". LED tested to harmonized standards and is substantially equivalent to the predicate device.
Ni-Cd Battery	**Li-Ion Battery**	The Syntec Vitman contained a Ni-Cd battery that allows 10 minutes of operational backup power. The ProCare Plus™ Vitrectomy System contains a Li-Ion battery that provides operational power for up to 8 hours. Batteries are rechargeable and substantially equivalent to the predicate device.
Operational and technological characteristics form the basis for the determination of substantial equivalence of the ProCare Plus Vitrectomy System with legally marketed predicate devices.		

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5.16 Non-Clinical Tests

The ProCare Plus Vitrectomy System has passed all safety tests for demonstrated compliance with the applicable non-clinical tests below:

Standard/Guideline	Title
IEC 60601-1	Medical equipment/medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical Electrical Equipment - Part 1: General requirements for safety to collateral Standard: Electromagnetic Compatibility requirements and tests.
EN ISO 15004-2	Ophthalmic instruments – Fundamental requirements and test methods -- Part 2: Light hazard protection
ISO 11137-1	Sterilization of Health Care Product Requirements for Validation and Routine Control-Radiation Sterilization
ISO 11137-2	Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose.
ISO 11737-1	Sterilization of medical devices-Microbiological methods-Part 1: Determination of a population of microorganisms on products.
ISO 11737-2	Sterilization of medical devices-Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
ISO 11607-1	Packaging for Terminally Sterilized Medical Devices
IEC 62471	Photobiological Safety of lamps and lamp systems

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In-House Testing	Title
P1-112411	Main AC Electrical System
P1-112511	Internal DC Electrical System
P1-112611	Pneumatic Cutting System
P1-112711	Pneumatic Air Exchange System
P1-112811	Vacuum System
P1-112911	Lightsource
P1-113011	Battery Performance Testing
P1-113111	Pneumatic Handpiece Testing
P1-113211	Ergonomics/Portable System Testing
P1-113311	Medical Air Gas Cylinders & Regulators
F P1-113411	Foot Control
P1-051112	Pneumatic Handpiece HSP Burst Testing

5.17 Summary of Non-Clinical Tests

Updated technology has been extensively tested to recognized standards. The technological characteristics affecting the performance of the system are substantially equivalent to those of the predicate devices previously listed.

The ProCare Plus Vitrectomy System will be manufactured in compliance with FDA and ISO quality system requirements. System validation and verification will demonstrate that the functional requirements and system specifications have been met prior to commercial release.

Based upon the design, intended use, indications for use, classification, and safety testing the ProCare Plus Vitrectomy System is substantially equivalent, in whole or part, to the listed predicate devices (K980480, K904909, and K896622).

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

VisionCare Devices, Inc.
c/o Mr. Kurtis Montegna
Regulatory Affairs Manager
1246 Redwood Blvd.
Redding, CA 96003

MAY 3 0 2012

Re: K120170
Trade/Device Name: ProCare Plus Vitrectomy System
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous aspiration and cutting instrument
Regulatory Class: II
Product Code: HQE
Dated: Not Dated
Received: May 18, 2012

Dear Mr. Montegna:

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

Enclosures

Indications for Use

510(K) Number (if known): K120170

Device Name: ProCare Plus Vitrectomy System

Indications For Use:

The VCD HSP VitCutter and Accessories is a single use (disposable) product intended for use in both anterior and posterior segment (vitrectomy) ophthalmic surgeries when used with a pneumatically-driven vitrectomy system or phacoemulsification system that has a pneumatically-driven vitrectomy module.

Prescription use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 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 K120170

Indications for Use

510(K) Number (if known): K120170

Device Name: ProCare Plus Vitrectomy System

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Removal of vitreous in cases of vitreous clouding, diabetic vitreal hemorrhaging, trauma, including contusions, penetrations, and intraocular foreign bodies; opacity, inflammation, endophthalmitis (bacterial or fungal), uvitis

- Removal of lens fragments after cataract surgery;
- Remove vitreous traction under the retina producing localized or complete retinal detachment;
- Removal of samples of vitreous for diagnostic purposes, i.e. endophthalmitis;
- Treatment of vitreous loss during cataract surgery;
- Clean vitreous strands from the cataract wound;
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