DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 3, 2017

PHAKOS
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681

Re: K162756
Trade/Device Name: PHAKOS Disposable Retinal Cryo Probe
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic Unit
Regulatory Class: Class II
Product Code: HRN
Dated: April 12, 2017
Received: April 13, 2017

Dear J.D. Webb:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Denise L. Hampton -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162756

Device Name

PHAKOS Disposable Retinal Cryo Probe

Indications for Use *(Describe)*

The PHAKOS Disposable Retinal Cryo Probe is for use in ophthalmic surgery in cryopexy for retinal detachment, cyclo destructive procedures in refractory glaucoma, extraction of fragments within the vitreous cavity, cataract extraction, and cryo destruction of lash follicles for trichiasis.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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*5*10(k) Summary: PHAKOS Disposable Retinal Cryo Probe

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	April 26, 2017
Submitted By	PHAKOS 62 Rue Kléber 93100 Montreuil FRANCE
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	PHAKOS Disposable Retinal Cryo Probe
Common Name	cryomatic probe
Classification Name	Cryophthalmic unit
Class	II
Product Code	HRN
CFR Section	21 CFR section 886.4170
Device Panel	Ophthalmic
Primary Predicate Device	Keeler Cryomaster Probes – Keeler Instruments, Inc. (K062412 & K112093)
Device Description	The PHAKOS Disposable Retinal Cryo Probe is a single use item used with cryopexy equipment. It produces an ice ball at the tip of the pencil allowing you to treat the detachment of the retina by welding the tissues together. The ice ball is the result of a specific gas released at a high pressure, N2O or CO2, allowing the welding of the tissues by burn.
Materials	Polyacetal (ASTM F1855) PVC (ASTM D1785) Polyamide (ISO 1874-PA11, E, 22-010) Aluminum (ASTM B221) Stainless steel (ASTM F899) Silastic Lexan (ASTM D3935)
Indications for Use	The PHAKOS Disposable Retinal Cryo Probe is for use in ophthalmic surgery in cryopexy for retinal detachment, cyclo destructive procedures in refractory glaucoma, extraction of fragments within the vitreous cavity, cataract extraction, and cryo destruction of lash follicles for trichiasis.

Technological Characteristics	**Characteristic**	**PHAKOS Disposable Retinal Cryo Probe**	**Keeler Cryomaster Probes**
	Indications for Use	Same	Same
	Disposable	Yes	Yes
	Cryogen Type	CO^2 or N^2O	CO^2 or N^2O
	Freeze system pressure regulation	Automatic	Automatic
	Freeze control	Footswitch	Footswitch
	Purge cycle	Automatic	Automatic
	Auto clean	Yes	Yes
	Audible indicator	Yes	Yes
	Cryo probe connection mechanism	Quick release	Quick release
	Disposable probe connection	Connected to the console via disposable probe adapter	Connected to the console via disposable probe adapter
	Freeze zone	End freeze	End freeze
	Construction	**Probe** Probe tip: Stainless steel Connector: Polyacetal Sleeve: Aluminum Tube: PVC Nozzle: Stainless steel Adapter: Stainless steel	**Probe** Probe tip: Stainless steel Connector: Polyacetal Sleeve: Aluminum Tube: PVC Nozzle: Stainless steel Adapter: Stainless steel
	Dimensions	Same	Same
	Sterilization	EO sterilized	EO sterilized
Substantial Equivalence Claimed to Predicate Devices	The PHAKOS Disposable Retinal Cryo Probe is fully identical to the predicate device in terms of intended use, design, materials used, mechanical safety and performances.		
Non-clinical Test Summary	The following non-clinical testing was performed: • The operation of the adapters for single use cryods on different equipment • EO residual measurement • Pyrogenicity was evaluated using the Limulus amebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level.		
Clinical Test Summary	No clinical studies were performed		
Conclusions: Non-clinical and Clinical	PHAKOS considers the Disposable Retinal Cryo Probe to be strictly equivalent in design, materials and processing to the predicate device listed above and has a similar IFU.		