June 02, 2020

PHAKOS
℅ J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, UT 84401

Re: K200911
Trade/Device Name: MIRA Adapter
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic unit
Regulatory Class: Class II
Product Code: HRN
Dated: March 30, 2020
Received: April 6, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Tieuvi Nguyen, Ph.D.
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200911

Device Name
MIRA Adapter

Indications for Use *(Describe)*
The PHAKOS Disposable Retinal Cryo Probe and Accessories 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

*5*10(k) Summary: MIRA ADAPTER

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

Date Prepared	May 28, 2020
Submitted By	PHAKOS 62 Rue Kléber 93100 Montreuil FRANCE o.aumaitre@phakos.com
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-5905810 Tele e-mail: jdwebb@orthomedix.net
Trade Name	MIRA ADAPTER
Common Name	cryomatic probe ADAPTER
Classification Name	Unit, Cryophthalmic, Ac-powered
Class	II
Product Code	HRN
CFR Section	21 CFR section 886.4170
Device Panel	Ophthalmic
Primary Predicate Device	PHAKOS Disposable Retinal Cryo Probe (K162756)
Reference Predicates	FRIGITRONICS ADAPTER (K180195)
Device Description	The cryoprobe ADAPTER is a mechanical accessory used to adapt the PHAKOS Disposable Retinal Cryo Probe to different cryosurgery generators found on the market; it is connected to the cryoprobe connector on the generator. The rear end piece receiving the cryoprobe is the same for all ADAPTERs; the body varies according to the generator used. The ADAPTER is fitted on the generator in the place of the original cryoprobe, and remains in position, while the PHAKOS Disposable Retinal Cryo Probe is plugged into the universal rear end piece.
Materials	Stainless steel per ASTM F899 Polyoxymethylene (acetal) per ASTM D6778
Substantial Equivalence Claimed to Predicate Devices	The MIRA ADAPTER is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

<table>
<tr><td>Indications for Use</td><td>The PHAKOS Disposable Retinal Cryo Probe and Accessories 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.</td></tr>
<tr><td>Summary of the technological characteristics compared to predicate</td><td>
<table>
<tr><th><u>Criteria</u></th><th><u>Demonstration of Equivalency</u></th></tr>
<tr><td>Intended Use</td><td>The intended use of the MIRA ADAPTER is the same as the other Phakos ADAPTERs.</td></tr>
<tr><td>Material</td><td>The PHAKOS MIRA ADAPTER uses the same material as the other PHAKOS ADAPTERs.</td></tr>
<tr><td>Design</td><td>The MIRA ADAPTER and the other PHAKOS ADAPTERs are equivalent in terms of shape,</td></tr>
<tr><td>Disposable probe connection</td><td>The disposable cryo probes are connected to the console via the MIRA ADAPTER and the other PHAKOS ADAPTERs.</td></tr>
</table>
</td></tr>
<tr><td>Non-clinical Test Summary</td><td>The following analyses were conducted:
creation of the ice ball
The results of these evaluations indicate that the MIRA ADAPTER is equivalent to predicate devices.</td></tr>
<tr><td>Clinical Test Summary</td><td>No clinical studies were performed</td></tr>
<tr><td>Conclusions: Non-clinical and Clinical</td><td>PHAKOS considers the MIRA ADAPTER to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.</td></tr>
</table>