



March 16, 2018

Phakos  
% J D Webb  
Authorized Contact Person  
The OrthoMedix Group, Inc.  
1001 Oakwood Blvd  
Round Rock, TX 78681

Re: K180195  
Trade/Device Name: Frigitronics adapter  
Regulation Number: 21 CFR 886.4170  
Regulation Name: Cryophthalmic unit  
Regulatory Class: Class II  
Product Code: HRN  
Dated: January 19, 2018  
Received: January 24, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Bradley S. Cunningham -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

## Indications for Use

510(k) Number (if known)

K180195

Device Name

Frigitronics 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.

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**510(k) Summary: Frigitronics Adapter**

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

|                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Date Prepared</b>                                        | March 09, 2018                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Submitted By</b>                                         | PHAKOS<br>62 Rue Kléber<br>93100 Montreuil<br>FRANCE<br>o.aumaitre@phakos.com                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Primary Contact</b>                                      | J.D. Webb<br>1001 Oakwood Blvd<br>Round Rock, TX 78681<br>512-388-0199 Tele<br>e-mail: jdwebb@orthomedix.net                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Trade Name</b>                                           | Frigitronics Adapter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Common Name</b>                                          | cryomatic probe adapter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Classification Name</b>                                  | Unit, Cryophthalmic, Ac-powered                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Class</b>                                                | II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Product Code</b>                                         | HRN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>CFR Section</b>                                          | 21 CFR section 886.4170                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Device Panel</b>                                         | Ophthalmic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Primary Predicate Device</b>                             | PHAKOS Disposable Retinal Cryo Probe (K162756)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Device Description</b>                                   | <p>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.</p> <p>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.</p> |
| <b>Materials</b>                                            | <p>Stainless steel per ASTM F899</p> <p>Polyoxymethylene (acetal) per ASTM D6778</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Substantial Equivalence Claimed to Predicate Devices</b> | The Frigitronics Adapter is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Indications for Use</b>                                  | 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.                                                                                                                                                                                                                                                        |

| <b>Summary of the technological characteristics compared to predicate</b> | <table> <tr> <th data-bbox="466 201 743 247"><u>Criteria</u></th><th data-bbox="743 201 1421 247"><u>Demonstration of Equivalency</u></th></tr> <tr> <td data-bbox="466 279 743 325">Intended Use</td><td data-bbox="743 279 1421 325">The intended use of the Frigitronics Adapter is the same as the other Phakos adapters.</td></tr> <tr> <td data-bbox="466 357 743 403">Material</td><td data-bbox="743 357 1421 403">The PHAKOS Frigitroncs Adapter uses the same material as the other PHAKOS adapters.</td></tr> <tr> <td data-bbox="466 434 743 480">Design</td><td data-bbox="743 434 1421 480">The Frigitroncs Adapter and the other PHAKOS adapters are equivalent in terms of shape,</td></tr> <tr> <td data-bbox="466 512 743 558">Disposable probe connection</td><td data-bbox="743 512 1421 558">The disposable cryo probes are connected to the console via the Frigitroncs Adapter and the other PHAKOS adapters.</td></tr> </table> | <u>Criteria</u> | <u>Demonstration of Equivalency</u> | Intended Use | The intended use of the Frigitronics Adapter is the same as the other Phakos adapters. | Material | The PHAKOS Frigitroncs Adapter uses the same material as the other PHAKOS adapters. | Design | The Frigitroncs Adapter and the other PHAKOS adapters are equivalent in terms of shape, | Disposable probe connection | The disposable cryo probes are connected to the console via the Frigitroncs Adapter and the other PHAKOS adapters. |
|---------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-------------------------------------|--------------|----------------------------------------------------------------------------------------|----------|-------------------------------------------------------------------------------------|--------|-----------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------|
| <u>Criteria</u>                                                           | <u>Demonstration of Equivalency</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |
| Intended Use                                                              | The intended use of the Frigitronics Adapter is the same as the other Phakos adapters.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |
| Material                                                                  | The PHAKOS Frigitroncs Adapter uses the same material as the other PHAKOS adapters.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |
| Design                                                                    | The Frigitroncs Adapter and the other PHAKOS adapters are equivalent in terms of shape,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |
| Disposable probe connection                                               | The disposable cryo probes are connected to the console via the Frigitroncs Adapter and the other PHAKOS adapters.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |
| <b>Non-clinical Test Summary</b>                                          | <p>The following analyses were conducted:</p> <ul style="list-style-type: none"> <li>• creation of the ice ball</li> </ul> <p>The results of these evaluations indicate that the Frigitroncs Adapter is equivalent to predicate devices.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |
| <b>Clinical Test Summary</b>                                              | <p>No clinical studies were performed</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |
| <b>Conclusions: Non-clinical and Clinical</b>                             | <p>PHAKOS considers the Frigitroncs Adapter to be 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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                 |                                     |              |                                                                                        |          |                                                                                     |        |                                                                                         |                             |                                                                                                                    |