October 25, 2018

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

Re: K173944
  Trade/Device Name: Endoculare Viewing Lenses and Silicone Ring
  Regulation Number: 21 CFR 886.1385
  Regulation Name: Polymethylmethacrylate (PMMA) Diagnostic Contact Lens
  Regulatory Class: Class II
  Product Code: HJK
  Dated: September 19, 2018
  Received: September 25, 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. 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/cfpmm/pmm.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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green

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)
K173944

Device Name
ENDOCULAR VIEWING LENSES AND SILICONE RING

Indications for Use (Describe)
The ENDOCULAR VIEWING LENSES AND SILICONE RING family allows visualizations of the retina, the vitreous humor, the lens, the iris, the angle of the anterior chamber, as well as other ocular structures during surgical procedures or consultation.

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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“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.”
**510(k) Summary: ENDOCULAR VIEWING LENSES AND SILICONE RING**

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

<table>
<thead>
<tr>
<th>Date Prepared</th>
<th>October 22, 2018</th>
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</thead>
<tbody>
<tr>
<td>Submitted By</td>
<td>PHAKOS</td>
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<tr>
<td></td>
<td>62 Rue Kléber</td>
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<td>93100 Montreuil</td>
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<td>FRANCE</td>
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<td>Primary Contact</td>
<td>J.D. Webb</td>
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<td></td>
<td>1001 Oakwood Blvd</td>
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<td>Round Rock, TX 78681 512-388-0199 Tele</td>
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<td></td>
<td>e-mail: <a href="mailto:jdwebb@orthomedix.net">jdwebb@orthomedix.net</a></td>
</tr>
<tr>
<td>Trade Name</td>
<td>Endocular Viewing Lenses and Silicone Ring</td>
</tr>
<tr>
<td>Common Name</td>
<td>Lens, Contact, Polymethylmethacrylate, Diagnostic</td>
</tr>
<tr>
<td>Classification Name</td>
<td>Polymethylmethacrylate (PMMA) diagnostic contact lens</td>
</tr>
<tr>
<td>Class</td>
<td>II</td>
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<tr>
<td>Product Code</td>
<td>HJK</td>
</tr>
<tr>
<td>CFR Section</td>
<td>21 CFR section 886.1385</td>
</tr>
<tr>
<td>Device Panel</td>
<td>Ophthalmic</td>
</tr>
<tr>
<td>Primary Predicate Device</td>
<td>Disposable Vitrectomy Lens, OCULAR Instruments, Inc. (K012096)</td>
</tr>
<tr>
<td>Secondary Predicate Devices</td>
<td>Disposable Vitrectomy Lens, VOLK Optical, Inc. (K050623/ K151961)</td>
</tr>
<tr>
<td></td>
<td>Family of Vitrectomy Lenses, SENSOR Medical Technology LLC (K140368/ K142715)</td>
</tr>
<tr>
<td>Device Description</td>
<td>The &quot;ENDOCULAR VIEWING LENSES AND SILICONE RING&quot; family includes devices comprised of an endocular viewing lens and/or of a cornea support that allows for stabilization of this lens on the eye. This range allows one to view the retina, the vitreous humor, the lens, the iris, the angle of the anterior chamber, as well as other ocular structures during surgical procedures or consultation.</td>
</tr>
<tr>
<td>Materials</td>
<td>Conventional lens:</td>
</tr>
<tr>
<td></td>
<td>PMMA polymethyl methacrylate</td>
</tr>
<tr>
<td>High Resolution lens:</td>
<td>OKP4 Polyester Optical Plastic</td>
</tr>
<tr>
<td>Flexible removable ring:</td>
<td>MED 4035 silicone</td>
</tr>
<tr>
<td>Silicone ring (alone):</td>
<td>MED 4035 silicone</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The endocular viewing lens is a passive device that is used to view the fundus of the eye by placing it on the cornea.</td>
</tr>
</tbody>
</table>
### Substantial Equivalence Claimed to Predicate Devices

The Endocular Viewing Lenses and Silicone Ring is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

### Indications for Use

The ENDOCULAR VIEWING LENSES AND SILICONE RING family allows visualizations of the retina, the vitreous humor, the lens, the iris, the angle of the anterior chamber, as well as other ocular structures during surgical procedures or consultation.

### Summary of the Technological Characteristics Compared to Predicate

<table>
<thead>
<tr>
<th>Device</th>
<th>PHAKOS</th>
<th>OCULAR</th>
<th>VOLK</th>
<th>SENSOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>The endocular viewing lens is a passive device that is used to view the fundus of the eye by placing it on the cornea.</td>
<td>Allow visualization of the ocular fundus, vitreous, and retinal structures during vitrectomy surgery.</td>
<td>For use as diagnostic lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.</td>
<td>Used in the examination of the eye fundus, retina and irido-corneal and vitreous bodies</td>
</tr>
</tbody>
</table>

#### Type of Lenses

- Vitrectomy
- Gonioprism
- Panoramic Wide Field
- 3-prism
- Capsulotomy
- Silicone Ring

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- Gonioprism
- Panoramic Wide Field
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- Vitrectomy
- Gonioprism
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- 3-prism
- Capsulotomy
- Silicone Ring

#### Comparison of Lenses

- All of the systems include the full range of Vitrectomy Lens, with the exception of the SENSOR not having a Wide-Angle Lens. The SENSOR has no HR Vitrectomy Lens
- All of the systems include Gonioprism Lens.
- All systems include a Panoramic Wide Field Lens. All of the systems include 3-prism Lens.
- All systems include a Capsulotomy Lens.

#### Material

- PMMA
- OKP 4 (acrylic)
- silicone
- PMMA
- Acrylic
- Glass
- Quartz
- PMMA
- Acrylic
- Glass
- PMMA

#### Non-clinical Test Summary

The following tests were performed:
- ISO 10993-5 In vitro cytotoxicity
- ISO 10993-10 Irritation
- ISO 10993-10 Sensitization

#### Clinical Test Summary

No clinical studies were performed
### Conclusions: Non-clinical and Clinical

PHAKOS considers the Endocular Viewing Lenses and Silicone Ring 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.