Largan Medical Co. Ltd.
% Jennifer Ting
RA Manager
Jens Medical Consulting Ltd
6F, No 39, Ln 224,
Luzhou Dist., New Taipei City, TW 247
Taiwan R.O.C

Re: K170286
Trade/Device Name: Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens,
Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens
for Astigmatism, Largan (hioxifilcon A) Daily Wear Soft
(hydrophilic) Contact Lens For Presbyopia
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: August 12, 2017
Received: August 24, 2017

Dear Jennifer Ting:

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 (DICE) 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 (DICE) 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
Indications for Use

Device Name
Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) contact Lens
Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) contact lens for ASTIGMATISM
Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) contact lens for PRESBYOPIA

Indications for Use (Describe)
The Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens is a Daily Wear Soft (hydrophilic) Contact Lens indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

The Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism is indicated daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters and astigmatic corrections are from -0.25 to -5.00 diopters.

The Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia is indicated daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters with add powers from +0.25 to +3.50 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less where the astigmatism does not interfere with visual acuity.

Eye care practitioners may prescribe the lens for either single-use disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for single-use disposable wear, the lens is to be discarded after each removal, therefore no cleaning or disinfecting is required. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

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.

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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."
1.1 Establishment Information:
Name: Largan Medical Co. Ltd.
Owner: Adam Lin
Title: CEO
Address: 2F., No. 14, 23rd Rd., Taichung Industrial Park, Nantun Dist., Taichung, 40850, Taiwan
Phone No.: 886-4-3600-0203
Fax No.: 886-4-3601-0203
E-mail: info@larganmed.com.tw

1.2 Contact Person:
Phone No.: 886-4-3600-0203
Fax No.: 886-4-3601-0203
Contact Name: Amy Tien
E-mail: amytien@larganmed.com.tw

1.3 Device Identification:
Proprietary Name: Largan (hioxifilcon A) Daily Wear Soft (Hydrophilic) Contact Lens
Common Name: Soft (hydrophilic) Contact Lenses
Classification Name: Lenses, Soft Contact, Daily Wear,
(21 CFR 886.5925, Product Code LPL)
Lenses, Soft Contact, Daily Wear (Disposable),
(21 CFR 886.5925, Product Code MVN)
Classification: II
Regulation Number: CRF 886.5925
Review Panel: Ophthalmic
Product Code: LPL/MVN

1.4 Legally Marketed Equivalent Device:
Predicate Device Name: AQUASOFT ALL-DAY & ALL-DAY T (hioxifilcon A) Daily Wear Contact Lens.
Manufacturer: ClearLab Pte Ltd.
510(k) Number: K052290
Product Code: LPL

1.5 Device Description:
The Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens is in hemispherical flexible shells for myopia, hyperopia, astigmatism and Presbyopia. The lens is made from HEMA containing UV blocker. The composition of the lens is 41% hioxifilcon A and 59% water. A light blue color tinted with “reactive Blue 247” is for handling visibility purpose. A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are 1.3% (<5%) in the UVB range of 280-315nm and 14.2% (<50%) in the UVA range of 316-380nm. It is supplied in a sterile state packaged in a buffered saline solution.

1.6 Indication for Use:
The **Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens** is a Daily Wear Soft (hydrophilic) Contact Lens indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

The **Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism** is indicated daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters and astigmatic corrections are from -0.25 to -5.00 diopters.

The **Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia** is indicated daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -10.00 to +3.00 diopters with add powers from +0.25 to +3.50 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less where the astigmatism does not interfere with visual acuity.

Eye care practitioners may prescribe the lens for either single-use disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for single-use disposable wear, the lens is to be discarded after each removal, therefore no cleaning or disinfecting is required. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

### 1.7 Technological characteristic

**Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens** characteristics:
- Diameter Range: 13.0 to 15.0 mm
- Base Curve: 8.0 to 9.0 mm
- Center Thickness: 0.102 mm for -1.00D (varies with power)
- Power: +3.00 to -10.00 D

**Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens for Astigmatism** characteristics:
- Diameter Range: 13.0 to 15.0 mm
- Base Curve: 8.0 to 9.0 mm
- Center Thickness: 0.102 mm for -1.00D (varies with power)
- Power: +3.00 to -10.00 D
- Cylinder: -0.25D ~ -5.00 D
- Axis: 10º to 180º (in 10º increments)

**Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens for Presbyopia** characteristics:
- Diameter Range: 13.0 to 15.0 mm
- Base Curve: 8.0 to 9.0 mm
- Center Thickness: 0.102 mm for -1.00D (varies with power)
- Power: +3.00 to -10.00 D
- Additional Powers: +0.25D ~ +3.50D

### 1.8 Comparison table:

The characteristic comparison to predicate device is summarized in the following table.
### Similarities and differences

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate (K052290)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Name</strong></td>
<td>Largan daily wear soft contact lens</td>
<td>AQUASOFT ALL-DAY &amp; ALL-DAY T Daily Wear Contact Lens</td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Largan Medical Inc.</td>
<td>ClearLab Pte Ltd.</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Myopia, Hyperopia, astigmatism, Presbyopia</td>
<td>Myopia, Hyperopia, astigmatism</td>
</tr>
<tr>
<td><strong>Lens Design</strong></td>
<td>aspherical, toric, or multifocal</td>
<td>spherical, toric</td>
</tr>
<tr>
<td><strong>Replacement Schedule</strong></td>
<td>Daily Wear</td>
<td>The same</td>
</tr>
<tr>
<td><strong>Chemical composition</strong></td>
<td>Hioxifilcon A</td>
<td>The same</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td>Group II (Nonionic, High water)</td>
<td>The same</td>
</tr>
<tr>
<td><strong>Water Content</strong></td>
<td>59 % (&gt;50%), 57 % (&gt;50%)</td>
<td></td>
</tr>
<tr>
<td><strong>Oxygen Permeability (DK, 35°C)</strong></td>
<td>22  (Fatt method)</td>
<td>20  (Fatt method)</td>
</tr>
<tr>
<td><strong>Base Curve Range (mm)</strong></td>
<td>8.0~9.0</td>
<td>8.0 ~ 9.2</td>
</tr>
<tr>
<td><strong>Diameter (mm)</strong></td>
<td>13.0~15.0</td>
<td>13.0 ~15.0</td>
</tr>
<tr>
<td><strong>Center Thickness</strong></td>
<td>Varies with design and power (0.102 mm at -1.00D)</td>
<td>Varies with design and power (0.08 mm at -3.00D)</td>
</tr>
<tr>
<td><strong>Powers</strong></td>
<td>-10.00D to +3.00D</td>
<td>-20.00D to +20.00D</td>
</tr>
<tr>
<td><strong>Refractive Index</strong></td>
<td>1.403</td>
<td>1.4058</td>
</tr>
<tr>
<td><strong>Light Transmittance</strong></td>
<td>90%</td>
<td>&gt; 95%</td>
</tr>
<tr>
<td><strong>Blue handling tint</strong></td>
<td>Reactive Blue 247</td>
<td>Reactive Blue 19</td>
</tr>
<tr>
<td><strong>Method of Manufacture</strong></td>
<td>Cast Molded</td>
<td>Cast Molded</td>
</tr>
</tbody>
</table>

1.9 Nonclinical Tests Performed

1.9.1 Physiochemical studies were conducted according to ISO 18369 First edition 2006-08-15, Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specifications for the lenses.

1.9.2 Toxicology studies report shows that the lenses are non-toxic and biocompatibility result is acceptable in ocular environment.

1.10 Clinical Studies

The technical characteristics, formulation, manufacturing process of the subject device are equivalent to AQUASOFT ALL-DAY & ALL-DAY T Daily Wear Contact Lens (K0052290) current marketed by CearLab Pte Ltd, therefore no clinical data is required.

1.11 Conclusion

Comparison to the predicate device for chemical composition, physical and optical properties, it shows that “Largan (hioxifilcon A) Daily Wear Soft (hydrophilic) Contact Lens” is as safe, as effective and performs as well as the predicate device.