510(k) Summary

Submitter Information:
IGEL Visioncare Pte. Ltd.
139 Joo Seng Road, #05-01 ATD Centre
Singapore 368362
Registration Number: 9614154

Contact Person: Mr Stephen D Newman, Chief Executive Officer
Telephone: +65 67491090
Fax: +65 62848534
Date Prepared: March 5, 2002

Device Name:
Common Name: Soft (Hydrophilic) Contact Lens
Trade/Proprietary Names:
- Igel 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
- Igel 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
- Igel 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens
Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:
The Specialty 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens, the Specialty 55 UV Multifocal
(methafilcon A) Soft (Hydrophilic) Contact Lens and the Specialty 55 UV Toric (methafilcon A) Soft
(Hydrophilic) Contact Lens were selected as the predicate devices.

The Igel 55 UV lenses are manufactured in the same facility, under the same quality system, using
the same moulding, tinting, packaging and sterilization processes. The Igel 55 UV lenses contain the
same UV blocking agent as the Specialty 55 UV lenses, and the manufacturing process for adding the
UV blocking agent is the same.

Description of Devices:
The Igel 55 UV, the Igel 55 UV Multifocal, and the Igel 55 UV Toric Daily Wear Contact Lenses
(methafilcon A) are hemispherical flexible shells which cover the cornea and a portion of the adjacent
sclera. The Igel 55 UV Contact Lens is available in a single vision lens design, the Igel 55 UV
Multifocal Contact Lens is available in an aspherical lens design, and the Igel 55 UV Toric Contact
Lens is available in a back surface toric design. The lens material (methafilcon A) is a hydrophilic
polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). A UV absorbing compound has been incorporated into the lens polymer. All lenses are tinted using the color additive Reactive Blue #19.

Comparison to Predicate Device

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>Igel 55 UV, Igel 55 UV Multifocal, and Igel 55 UV Toric Soft (Hydrophilic) Contact Lenses for Daily Wear</th>
<th>Specialty 55 UV, Specialty 55 UV Multifocal and Specialty 55 UV Toric Soft (Hydrophilic) Contact Lenses for Daily Wear</th>
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</thead>
<tbody>
<tr>
<td>Submission number</td>
<td>methafilcon A</td>
<td>K003526</td>
</tr>
<tr>
<td>Material</td>
<td>Hydrophilic Lens Group 4</td>
<td>Hydrophilic Lens Group 4</td>
</tr>
<tr>
<td>Material classification</td>
<td>myopia, hyperopia, presbyopia and astigmatism</td>
<td>myopia, hyperopia, presbyopia and astigmatism</td>
</tr>
<tr>
<td>Water content</td>
<td>55%</td>
<td>55%</td>
</tr>
<tr>
<td>Visible light transmittance</td>
<td>90.3%</td>
<td>90.3%</td>
</tr>
<tr>
<td>UV transmittance</td>
<td>&lt; 10%</td>
<td>&lt; 10%</td>
</tr>
<tr>
<td>Dk (35°C)</td>
<td>18.9 x 10^{-11}</td>
<td>18.9 x 10^{-11}</td>
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<tr>
<td>Powers</td>
<td>+20.00 to -20.00 Diopters</td>
<td>+20.00 to -20.00 Diopters</td>
</tr>
<tr>
<td>Color</td>
<td>blue visibility, Reactive Blue #19</td>
<td>Reactive Blue #19</td>
</tr>
<tr>
<td>Refractive index</td>
<td>1.42</td>
<td>1.42</td>
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<tr>
<td>Specific gravity</td>
<td>1.06</td>
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<tr>
<td>Method of manufacture</td>
<td>Moulded</td>
<td>Moulded</td>
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</table>

Indications for Use:

The Igel 55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The Igel 55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear is indicated for the correction of presbyopia in myopic and hyperopic eyes in aphakic or not-aphakic persons with non-diseased eyes who exhibit no more than 2.00 Diopters of astigmatism and can obtain satisfactory visual acuity, in a power range of +4.00 to -5.00 Diopters and have near add requirements up to 3.00 Diopters.

The Igel 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 7.00 Diopters.
The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

**Description of Safety and Substantial Equivalence:**

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Igel 55 UV, the Igel UV Multifocal and the Igel 55 UV Toric (methafilcon A) Contact Lenses for Daily Wear. Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. Extraction and analysis of the lenses showed no detectable extractables. The Igel 55 UV lenses passed the requirements of sterility and stability testing.

**Conclusion:**

Information submitted in the 510(k) establishes that the Igel 55 UV, the Igel 55 UV Multifocal and the Igel 55 UV Toric Contact Lenses (methafilcon A) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.
Mr. Stephen D. Newman  
Chief Executive Officer  
IGEL Visioncare PTE LTD  
139 Joo Seng Road #05-01 ATD Centre  
Singapore 368362  

Re: K020855  
   Trade/Device Name: IGEL 55UV (methafilcon A), IGEL 55UV Multifocal (methafilcon A)  
   and IGEL 55UV Toric (methafilcon A) Soft (hydrophilic) Contact  
   Lenses for Daily Wear  
   Regulation Number: 21 CFR 886.5925  
   Regulation Name: Soft (hydrophilic) Contact Lens  
   Regulatory Class: Class II  
   Product Code: LPL  
   Dated: March 5, 2002  
   Received: March 15, 2002  

Dear Mr. Newman:  

We have reviewed your Section 510(k) premarket notification of intent to market the device  
referred to 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.  

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it  
may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97).

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address:
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health
INDICATIONS STATEMENT

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✔ OR Over-the-Counter Use

Division Sign-Off
Division of Ophthalmic Ear, Nose and Throat Devices

510(k) Number K 020855