NOV 20 1997

K973192

# 510 (k) Summary

**SUBMITTER:**


| | |
|---|---|
| Company: | Specialty UltraVision, Inc.<br>307 Orchard City Drive<br>Suite 100<br>Campbell, CA 95008 |
| Contact Person: | Ivalee Cohen<br>Director, Regulatory and Clinical Affairs |
| Telephone:<br>FAX: | 408-341-0700<br>408-341-0717 |
| Date Prepared: | November 17, 1997 |


**DEVICE NAME:**

| | |
|---|---|
| Common Name: | Soft Contact Lens |
| Trade Names: | **Specialty 42** (hefilcon A) Hydrophilic Contact Lens for Daily Wear (clear and visibility tinted)<br><br>**Specialty T-42** (hefilcon A) Hydrophilic Toric Contact Lens for Daily Wear (clear and visibility tinted) |
| FDA Classification: | Class II |

**SUBSTANTIALLY EQUIVALENT TO:**

**Flexlens** (hefilcon A) Hydrophilic Contact Lens for Daily Wear, Paragon Vision Sciences
**Flexlens Toric** (hefilcon A) Hydrophilic Contact Lens for Daily Wear, Paragon Vision Sciences

Specialty 42 (hefilcon A) Hydrophilic Contact Lens for Daily Wear (clear and tinted) and Specialty T-42 (hefilcon A) Hydrophilic Toric Contact Lens for Daily Wear (clear and visibility tinted) are substantially equivalent in physical, optical and chemical properties, as well as material of manufacture, indications for use and method of manufacture to Paragon Vision Sciences' Flexlens (hefilcon A) Hydrophilic Contact Lens for Daily Wear and Flexlens Toric (hefilcon A). Flexlens lenses received marketing approval pursuant to N17-976. Specialty UltraVision, Inc. has received from the manufacturer of the hefilcon A contact lens buttons, BENZ Research and Development Corp., the right to reference their master file (MAF 872) and 510(k) K972807 regarding the manufacture and distribution of this material.

The hefilcon A lens material has been placed in Group 1, low water, and non-ionic polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition, May, 1994.

**DESCRIPTION OF THE DEVICE:**

Soft contact lenses are hemispherical shells manufactured of a copolymer of 2-hydroxyethyl methacrylate (HEMA) and n-vinyl-2-pyrrolidone (NVP), which yield the appearance of lenses, which are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves which conform to the shape of the radius of the cornea and center over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (multiple foci). Each lens provides corrective power, which is to correspond to the refractive power of the eye to which it is being treated. Each lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens which is generally of a diameter greater than 6 mm. Secondary and tertiary curves as well as beveled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort.

**SIMILARITIES AND DIFFERENCES**

| ***PARAMETER*** | ***Specialty 42 Hydrophilic Contact Lens for Daily Wear (clear and visibility tinted)*** | ***Flexlens Hydrophilic Contact Lens for Daily Wear*** |
|---|---|---|
| ***material*** | hefilcon A | hefilcon A |
| ***indication for use*** | myopia and hyperopia | myopia, hyperopia and astigmatism |
| ***water content*** | 42% | 42% |
| ***light transmittance*** | >95% | >95% |
| ***Dk (35° C)*** | $13.25 \times 10^{-11}$ | $13.13 \times 10^{-11}$ |
| ***powers*** | +20.00 to -20.00 Diopters | +20.00 to -20.00 Diopters |
| ***color*** | clear and blue visibility | clear |
| ***specific gravity*** | 1.031 | 1.044 |
| ***refractive index*** | 1.417 | 1.413 |
| ***Method of manufacture*** | Lathe cut | Lathe cut |

**INDICATIONS FOR USE:**

The Specialty 42 and the Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lenses (clear and visibility tinted) are 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.

Eye care practitioners may prescribe the lenses for daily wear in a Frequent Replacement program with scheduled replacement. The lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems.

## PARAMETERS AVAILABLE:

**Specialty 42 (hefilcon A) Hydrophilic Contact Lens (clear and visibility tinted)**

| | |
|---|---|
| Powers: | +20.00 to -20.00 Diopters |
| Diameter: | 14.3 mm |
| Base Curve: | 8.6 mm |

**Specialty T-42 (hefilcon A) Hydrophilic Toric Contact Lens (clear and visibility tinted)**

| | |
|---|---|
| Powers: | +1.00 to -7.00 Diopters |
| Diameter: | 14.5 mm |
| Base Curve: | 8.3 mm, 8.6 mm. And 8.9 mm |
| Cylinder powers: | -0.75, -1.25, -1.75, -2.25, -2.75, -3.25 Diopters |
| Axes: | 10°, 20°, 80°, 100°, 160°, 170°, 180° |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1997

Ms. Ivalee Cohen
Director of regulatory and Clinical Affairs
Specialty Ultra Vision, Inc.
84 West Main Street
Freehold, NJ 07728

Re: K973192
Trade Name: Specialty 42 (hefilcon A) Hydrophilic Contact Lens for Daily Wear and Specialty T-42 (hefilcon A) Hydrophilic Toric Contact Lens for Daily Wear (clear and visibility tinted, lathe cut)
Regulatory Class: II
Product Code: 86 LPL
Dated: August 18, 1997
Received: August 25, 1997

Dear Ms. Cohen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

# INDICATIONS STATEMENT

**510(k) Number:** K973192

**Device Name:**

**Specialty 42** (hefilcon A) Hydrophilic Contact Lens for Daily Wear (clear and visibility tinted)

**Specialty T-42** (hefilcon A) Hydrophilic Toric Contact Lens for Daily Wear (clear and visibility tinted)

**Indications For Use:**

The Specialty 42 and the Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lenses (clear and visibility tinted) are 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.

Eye care practitioners may prescribe the lenses for daily wear in a Frequent Replacement program with scheduled replacement. The lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems.

**(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 _____

(Optional Format 1-2-96)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973192