K023530

510 (k) Summary

1.0 Name and address of submitter

Westcon Contact Lens Company, Inc.
611 Eisenhauer Street
Grand Junction, CO. 81503

NOV 2 6 2002

Contact Person Carol Noble
970-245-3845
Fax 970-245-4516

Date Prepared 10/14/02

2.0 Name of Device

- **Trade Name**:

  Spherical:
  Horizon 38 (polymacon) and Horizon 38 Westint (polymacon)

  Toric:
  Westhin 38 Soft Toric (polymacon) and Westhin 38 Soft Toric Westint (polymacon)

- **Common Name**: Daily Wear Soft Contact Lens

- **Generic (USAN) Name**: Polymacon

- **Classification Name**: Soft Hydrophilic Contact Lens

3.0 Indications

The Horizon 38 (polymacon), Horizon 38 Westint (polymacon), Westhin 38 Soft Toric (polymacon) and Westhin 38 Soft Toric Westint (polymacon) are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopic and astigmatism) in aphakic and/or not-aphakic persons with nondiseased eyes.
The lens may be disinfected using either a heat or chemical system .

8.0 510 (k) Summary

4.0 Device Description

The soft contact lenses that are manufactured from W-38 lens blanks, **clear** or **tinted**, can be lathe cut into a hemispherical shell that are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves that conform to the shape of the radius of the cornea and center over the apex of the cornea to provide correction of ametropia (myopia, hyperopic and astigmatism). Each lens provides corrective power, which corresponds 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, generally of a diameter greater than 6 mm. The primary and secondary, as well as, beveled edge configurations are built into the lens for the purpose of aiding on the lens centration and comfort.

5.0 Substantially Equivalent To:

Westcon will be claiming equivalency to our own contact lenses that are currently FDA approved in 510(k) K963837.

6.0 Summary of Safety and Effectiveness

W-38 (polymacon) lens blanks were subjected to leachability studies and showed no identifiable evidence of tint pigment leaching.

7.0 Technical Summaries

7.1 Toxicology:

Cytotoxicity, systemic toxicity and ocular irritation studies were. Test results showed no evidence of cellular or systemic toxicity, or ocular irritation.

8.0 510 (k) Summary

7.2 Physical/Optical Characteristics

Light transmittance, refractive index, water content, linear expansion, radial expansion and tensile strength were determined. A comparison of data from these studies showed that the W-38 polymacon is equivalent in physical and optical characteristics as 510(k) K963837

7.3 Microbiology

There will be no changes to the validated process in 510(k) K954524

7.4 Compatibility

The spectra measurement after the numerous cleaning and disinfecting cycles remained the same as the before measurement.

7.5 Shelf Life

The three year shelf life study has been started on the lenses manufactured from W-38 and will be completed later this year. The packaging remains the same as 510(k) K954524 and 510(k) K963837.

8.0 Conclusion

In conclusion, it is Westcons' conviction that the data submitted shows that manufacturing with W-38 polymacon instead of Benz's polymacon material does not raise different questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2002

Westcon Contact Lens Co., Inc.
c/o Ms. Carol Noble
Management Representative
611 Eisenhauer Street
Grand Junction, CO 81505

Re: K023530
Trade/Device Name: The Horizon 38 (polymacon), Horizon 38 Westint (polymacon), Westhin 38 Soft Toric (polymacon) and Westhin 38 Soft Toric Westint (polymacon) 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: October 14, 2002
Received: October 21, 2002

Dear Ms. Noble:

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.

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.

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), please contact the Office of Compliance at (301) 594-4692. 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" (21CFR 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

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 FOR USE STATEMENT

Device Name:

Horizon 38 (polymacon), Horizon 38 Westint (polymacon), Westhin 38 Soft Toric (polymacon) and Westhin 38 Soft Toric Westint (polymacon)

Indication of Use:

The Horizon 38 (polymacon), Horizon 38 Westint (polymacon), Westhin 38 Soft Toric (polymacon) and Westhin 38 Soft Toric Westint (polymacon) are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopic and astigmatism) in aphakic and/or not-aphakic persons with nondiseased eyes.
The lenses may be disinfected using either a heat or chemical system .

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

E. G. , Ph.D.

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

510(k) Number K023530

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109
(Optional Format 1-2-96)