

Summary of Safety and Effectiveness

I. General Information

- A. Device Generic Name: methafilcon A hydrophilic contact lenses
- B. Device Trade Names: Horizon 55 EW and Horizon 55 EW Westint
(methafilcon A) Soft Hydrophilic Contact Lenses for
Extended Wear
- C. Applicant's Name and Address: Westcon Contact Lens Co., Inc.
611 Eisenhower Street
Grand Junction, CO 81505
- D. Premarket Approval Application (PMA) Number: P990072
- E. Date of Notice of Approval to Applicant: AUG 22 2000

II. Indications

The Horizon 55 EW and Horizon 55 EW Westint (methafilcon A) Soft Hydrophilic Contact Lenses for Extended Wear are indicated for extended wear from 1 to 7 days between removal for cleaning, rinsing and disinfecting as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lenses may be worn by persons who exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

III. Center for Devices and Radiological Health (CDRH) Decision

The application includes by reference the data in PMA P850078 and related supplements for the Kontur Soft EW (methafilcon A) Hydrophilic Contact Lens. Kontur Kontakt Lens Co., Inc., in conjunction with two other companies, including Coast Vision, Inc., conducted a clinical study of the methafilcon A contact lens material for daily wear and extended wear. Kontur Kontakt Lens Co., Inc., having joint ownership of the data, received approval of P850078/S1 for the extended wear lens under a licensing agreement from Coast Vision, Inc. (P850079/S1), on June 25, 1986. Kontur Kontakt Lens Co., Inc. has authorized Westcon Contact Lens Co., Inc. to incorporate by reference the information contained in its approved PMA and related supplements to manufacture the lenses by the lathing technique.

CDRH approval of the Westcon Contact Lens Co., Inc. PMA is based on (1) the safety and effectiveness data contained in PMA P850078 and related supplements and (2) the results of the FDA inspection of Westcon Contact Lens Co., Inc. manufacturing facility. A copy of the approval order for P850078/S1 and the summary of the safety and effectiveness data for the Coast Vision, Inc. PMA supplement, P850079/S1 appears in Attachment A.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. CD RH issued an approval order on AUG 22 2000 . The applicant's manufacturing facility was inspected on APR 28 2000 , and was found to be in compliance with the device Good Manufacturing Practice regulations.

The device shelf-life has been established and approved at 3 years.

III. Potential Adverse Effects of the Device on Health

Potential adverse effects on health resulting from the use of this device are listed in the package insert under "ADVERSE REACTIONS" (Attachment B).

IV. Conditions of Approval

In addition to the standard "Conditions of Approval" enclosed with the approval order, the subject devices are limited to prescription use in accordance with 21 CFR 801.109. A draft copy of the approved package insert is attached (Attachment B). Copies of final printed labeling are available to interested persons for inspection at:

Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Attachments A and B



DEPARTMENT OF HEALTH & HUMAN SERVICES

Attachment A

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 25 1986

David G. Ewell, O.D.
President
Kontur Kontakt Lens Co., Inc.
200 South Garrard Blvd.
Richmond, California 94804

Re: P850078/S1
Kontur Soft EW (methafilcon A)
Hydrophilic Contact Lens
Filed: October 2, 1985
Amended: June 5, 1986

Dear Dr. Ewell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration has completed its review of your premarket approval application (PMA) supplement for the spherical Kontur Soft EW (methafilcon A) Hydrophilic Contact Lens. The lens is indicated for extended wear from 1 to 21 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. The lens is indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters (D) or less that does not interfere with visual acuity. The lens ranges in powers from -10.00 D to +10.00 D. The lens is to be disinfecting using a chemical lens care system. The PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). The shelf-life for the referenced device has been established and approved as 3 years. You may begin production and marketing of the device upon receipt of this letter.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon written request. In addition, the notice will state that a copy of all approved labeling (which may be a draft of the final labeling) is available for public inspection at CDRH. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (act).

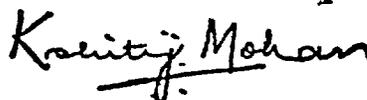
CDRH approval is subject to full compliance with the conditions described in the enclosure. Additionally, the sale, distribution, and use of the device shall be restricted to prescription use in accordance with 21 CFR 801.109.

All stated requirements are subject to change upon publication of a final premarket approval procedural regulation. Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You shall submit all required documents in triplicate to the Food and Drug Administration, Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910. You shall refer to the above PMA number in all further correspondence to expedite processing.

If you have any questions concerning this approval order, please contact Mr. David M. Whipple at (301) 427-7940.

Sincerely yours,



Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Summary of Safety and Effectiveness

I. General Information

- A. Device Generic Name: methafilcon A hydrophilic contact lens
- B. Device Trade Name: Hydrasoft XW (methafilcon A) Hydrophilic Contact Lens
- C. Applicant's Name and Address: Coast Vision, Inc.
18368 Enterprise Lane
Huntington Beach, California 92648
- D. Premarket Approval Application (PMA) Supplement Number: P850079/S1
- E. Date of Panel Recommendation: May 23, 1986
- F. Date of Notice of Approval to Applicant: JUN 25 1986

II. Indications

The spherical Hydrasoft (methafilcon A) Hydrophilic Contact Lens (hereafter referred to as the Hydrasoft XW Lens) is indicated for extended wear from 1 to 21 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lens is indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are myopic or hyperopic. The lens may be worn by persons who may exhibit refractive astigmatism of 1.50 diopters (D) or less that does not interfere with visual acuity. The lens ranges in powers from -10.00 D to +10.00 D. The lens is to be disinfected using a chemical lens care system only.

III. Device Description

The Hydrasoft XW Lens is a hydrophilic lens made from methafilcon A material.

Physical parameters of the lens are:

Refractive index: 1.415

Light transmission: 98.8%

Surface character: hydrophilic

Water content: 45%

Oxygen permeability: 31.3×10^{-9} (cm/sec) mL O₂/mL X mmHg at 25° C
measured by Schema Versatæe model 920 connected
to a polarographic cell

Dimensions of the lens are:

Base curve: 8.6 mm
Chord diameter: 15.00 mm
Center thickness: 0.06 mm
Lens powers: -10.00 D to +10.00 D

IV. Alternative Practices or Procedures

Alternative practices or procedures available to the patient are the use of other extended wear or daily wear contact lenses, or spectacles for the same indication.

V. Summary of Studies

A. Preclinical:

The PMA includes by reference, to the original PMA P820017 and all related supplements, the results of toxicological, microbiological, chemistry and manufacturing data and results. The results of these data provide reasonable assurance that the lens material is safe when manufactured into a lens for use in a clinical study and has a shelf-life of 3 years.

B. Clinical:

Purpose of the Study

The purpose of this clinical study was to demonstrate the safety and effectiveness of the device for its intended use. The clinical study was conducted in accordance with "Clinical Guidelines, Testing Guidelines for Class III Contact Lenses," an FDA guideline dated May 1983.

Patient Selection Criteria

Patients in this study were to meet the following criteria:

1. have need of an optical correction;
2. have spherical ametropia;
3. have reasonable expectation of improvement in visual acuity with contact lenses;
4. use no ocular medication; and
5. have nondiseased eyes which are normal or which have a pre-existing ocular condition which should not be expected to interfere with the patient's ability to wear the contact lens successfully. Such conditions should be adequately documented.

Study Population

A total of 152 patients (302 eyes) was enrolled by 11 investigators into the clinical study. Of the 152 enrolled patients, 106 patients (210 eyes) completed the 12-month study, 19 patients (38 eyes) remained active (10 patients had not completed the 12-month study period, and 12-month visit forms had not been received by the applicant for 9 patients at the time the PMA supplement was submitted to the Center for Devices and Radiological Health (CDRH) for review). Twenty-seven patients (54 eyes) were discontinued from the study. Of the 106 completed patients, there were 48 males, 54 females, and 4 with sex not reported, with ages ranging from 15 to 55 years. The completed patients included 184 myopic eyes and 26 hyperopic eyes. All patients in the study were not-aphakic except one. For completed patients pre-existing pathologies were reported as abnormal pupil (1 eye), abnormal retina (1 eye), exotropia (3 eyes), corneal edema (1 eye), neovascularization (1 eye), staining (1 eye), infection (5 eyes), and pinguecula; punctate keratitis (3 eyes). Lenses used in this study ranged in powers from +20.00 D to -9.75 D. All patients in the study used chemical lens care systems. Previous lens wear experience was reported as successful daily wear for 179 eyes, successful extended wear for 4 eyes, unsuccessful daily wear for 27 eyes, no previous lens wear experience for 90 eyes, and unreported for 2 eyes.

Study Period

The study was initiated on November 29, 1983. The cut-off date for clinical data in the PMA was July 1, 1985. One year of extended wear was required for completed patients.

Findings

1. Safety:

Adverse Reactions

In evaluating this device, an adverse reaction was considered to be a serious vision-threatening problem that was unanticipated, but which might have been attributed to the use of the study device.

There was one corneal ulcer reported during the course of this study. The corneal ulcer was reported at the 2-week visit along with grade 3 edema, grade 1 iritis, and grade 2 staining. This patient was discontinued from the study but continued to be seen at follow-up visits to monitor the conditions. At the next visit the patient had grade 1 edema with the ulcer clearing. Five days later all findings for this patient were normal. The investigator reported the ulcer followed a scratched cornea caused by the patient removing the lens.

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Conclusion:

The Center for Devices and Radiological Health (CDRH) has determined that the causal reason and outcome of the adverse reaction does not raise a significant safety concern when the lens is used in accordance with the approved labeling.

Slit Lamp Findings

A positive slit lamp finding is considered to be a routinely occurring complication that would be expected with or without the presence of contact lenses. The degree of severity can range from very slight to serious. At the least severe, the findings present no medical concern and are noticeable only by microscopic slit lamp examination. In a severe state, the findings require medical treatment.

Slit lamp examinations were performed initially (first visit with lenses) and periodically throughout the study. The applicant used the slit lamp quantification scheme "Classification of Slit Lamp Observations" as outlined in the FDA guideline.

The positive slit lamp findings for the 106 patients (210 eyes) completing the study were reported as follows:

Slit Lamp Finding	No. Eyes	Initial* Visit	Follow-up Visits	Final Visit
	188		1,607	210
Edema				
Grade 1		4	75	8
Grade 2		0	5	0
Grade 4		0	2	0
Neovascularization				
Grade 1		0	2	2
Staining				
Grade 1		0	34	2
Grade 2		0	7	0
Grade 3		0	1	0
Injection				
Grade 1		6	82	7
Grade 2		0	3	0
Iritis				
Grade 1		0	2	0
Other				
Grade 1		0	6	0
Grade 2		0	2	0

*22 eyes missed the first visit (2 to 4 hours) with lens, but were available for the 1-week visit.

One patient with handling problems was reported to have grade 2 edema in both eyes at the 1-month visit and again at the 3-month visit in one eye. All findings were normal for this patient when seen 18 days after the 4-month visit. One patient had grade 2 edema in one eye at the 2-month visit. The lens was replaced, and the condition cleared by the next visit. One patient had grade 2 edema at the 2-week visit which cleared by the 1-month visit. One patient had grade 4 edema in both eyes at the 4-month visit. The condition cleared by the next visit.

One patient had grade 3 staining at the 5-month visit due to allergy to thimerosal. The lens was replaced and the patient instructed to use thimerosal free solutions. All findings were normal at the next visit. One patient accounted for 4 grade 2 stainings. The patient had grade 2 staining in both eyes at the 4-month visit which cleared by the 5-month visit and reoccurred at the 8-month visit. The patient was changed to daily wear lenses, and all findings were normal. One patient had grade 2 staining at the 3-month visit which cleared by the 5-month visit.

One patient had grade 2 injection at the 2-month visit along with burning, itching, and tearing. At the 5-month visit all findings were normal for this patient.

Grade 2 "Other" was reported as subepithelial infiltrates for one patient at the 5-month visit. The lens was replaced, and all findings were normal.

Positive slit lamp findings above grade 2 for discontinued patients showed only 1 grade 3 edema finding in 224 follow-up visits. Grade 1 and 2 slit lamp findings were only slightly more frequent than for completed patients.

Conclusion:

The incidence and severity of positive slit lamp findings for discontinued patients were comparable to those for the completed patients in this study. These findings do not raise any significant concerns about the safety of the device for its intended use.

Symptoms, Problems and Complaints

Patient symptoms, problems and complaints were reported by the investigators at each patient visit. A total of 2,638 patient eyes were examined during the course of the study, and multiple patient symptoms, problems and complaints were reported as follows:

Symptoms, Problems and Complaints	No. Incidences
Blurred vision	106
Cleaning/handling	65
Tearing	37
Itching	35
Deposits	29
Burning	28
Dryness	23
Photophobia	21
Halo	8
Soiled lens	7
Redness	6
Comfort	5
Red eye	5
Excessive secretions	4
Flare	3
Cleaning	2
Headache	2
Fogged vision	2
Mild GPC*	2
Corneal ulcer	1
Scratchy	1
Lens loose	1
Discolor	1
Lump	1

*Giant papillary conjunctivitis

Conclusion:

The patient symptoms, problems and complaints reported during this study are within expected limits and do not raise any significant concerns about the safety and effectiveness of the device.

2. Effectiveness:

Visual Acuity

Visual acuity for the 210 eyes completing the study was reported as follows:

VA	No. Eyes	Initial Best Corrected	Initial with Lens	Final with Lens
		210	210	210
20/20 or better		192	168	181
20/25		12	16	21
20/30		5	5	6
20/40		0	1	1
20/50		1	2	1
Not available		0	18	0

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For the 210 eyes completing the study, visual acuity decreased 2 or more Snellen lines for 3 eyes for 2 patients. Visual acuity for one patient (2 eyes) changed from 20/20 to 20/30. The patient required a power change in both lenses. New lenses were dispensed, and visual acuity was 20/20 in both eyes. One patient was fit for monovision. The left eye was over corrected for good near vision.

Conclusion:

CDRH has concluded that a decrease of 1 Snellen line is not unusual in a contact lens study due to measuring techniques and normal fluctuation and is not significant in terms of visual acuity. The visual acuity results of this study demonstrate that the incidence of decreased vision for patients is within the expected limits for such patients. CDRH has determined that the decreases were not caused by ocular problems associated with contact lens wear. The visual acuity results in this study demonstrate the effectiveness of the device in correcting visual acuity in myopic and hyperopic not-aphakic eyes.

Lens Wearing Time

At the 6-month visit 136 of 178 eyes were wearing the lens from 7 to 14 days before removal. At the 12-month visit 142 of 194 eyes wore lenses from 7 to 14 days before removal and 30 eyes wore lenses for more than 30 days before removal. The major reason for lens removal was cleaning.

Conclusion:

The lens wearing time data provide reasonable assurance that the lens can be worn from 1 to 21 days as recommended by the eye care practitioner between removals without concerns regarding the safety or effectiveness of the device.

Discontinued Patients

A total of 27 patients (54 eyes) discontinued during the course of this study. Reasons for discontinuing the study were as follows:

<u>Reason</u>	<u>No. Eyes</u>
Unsatisfactory fit, all reasons related to	10
Patient motivation	8
Deposits and soiled lenses	8
Patient lost-to-follow-up	8
Comfort, all reasons related to	8
Visual acuity, all reasons related to	6
Dryness and redness	2
Reaction to solution	2
Slit lamp finding (GPC)	2
Conclusion:	

The reasons for and incidence of discontinuance in this clinical study are expected and do not raise any significant concerns regarding the safety or effectiveness of the device for its intended use.

Lens Replacements

There were 107 lenses replaced during the course of this clinical study. Reasons for lens replacements were as follows:

<u>Reason</u>	<u>No. Replacements</u>
<u>Physiological</u>	
Visual acuity	17
Visual acuity/deposits	8
Fit	7
Fit/vision	1
Red eye infiltrates	1
<u>Physical</u>	
Deposits	25
Lost	17
Lost/damaged	15
Soiled lens	6
Damaged	5
GPC	2
Mucous	1
Handling thin lens	1
No reason given	1

Conclusion:

The rate of lens replacements in this clinical study is expected when fitting soft (hydrophilic) contact lenses for extended wear.

VI. Potential Adverse Effects of the Device on Health

Potential adverse effects on health resulting from the use of this device are indicated in the package insert under "Adverse Reactions" (Attachment A).

VII. Conclusions Drawn From the Studies

The data provide reasonable assurance that the device is safe and effective for its intended use.

VIII. Panel Recommendation

On May 23, 1986, the Ophthalmic Devices Panel unanimously recommended approval of the PMA subject to the conditions that all administrative requirements be met and that the applicant be in compliance with the device Good Manufacturing Practice regulations.

IX. CDRH Decision

CDRH concluded that the applicant has met the above conditions. Based upon this conclusion, upon information in the PMA and upon review of the labeling, CDRH concurred with the Panel recommendation and approved the application and draft final labeling on

The device shelf-life has been established and approved as 3 years. Based on an on-site inspection on October 6 and 12, 1982 and a review of the firm's regulatory history, the manufacturing facility is regarded as in compliance with the device Good Manufacturing Practice regulations.

X. Conditions of Approval

In addition to the standard "Conditions of Approval" (Attachment B), the subject device is limited to prescription use in accordance with 21 CFR 801.109 and is limited to use with the chemical lens care system specified in the approved labeling. A copy of the approved draft package insert is attached (Attachment A). Copies of approved draft labeling are available to interested persons for inspection at:

Food and Drug Administration
Center for Devices and
Radiological Health
PMA Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Attachments A and B

PACKAGE INSERT

Hydrasoft XW (methafilcon A) Hydrophilic Contact Lens

DESCRIPTION

The Hydrasoft XW (methafilcon A) Hydrophilic Contact Lens is a hemispherical shell of approximately 15mm chord diameter, 0.06mm thickness, power range of -10.00 to +10.00, and base curve of 8.60mm. The lens material is a hydrophilic polymer of hydroxyethylmethacrylate. The lens consists of 45% methafilcon A and 55% water by weight when immersed in normal saline. The material has a refractive index of 1.415 and an oxygen permeability of 31.3×10^{-9} (cm/sec) ml O₂/ml X mmHg at 25° C as measured by Schema Versatae model 920 connected to a polarographic cell. The surface character of the lens is hydrophilic. The light transmittance is 98.8%.

ACTIONS

When placed on the human cornea in its hydrated state, the Hydrasoft XW lens acts as a refractive medium to focus light rays on the retina.

INDICATIONS

Hydrasoft XW lens is indicated for extended wear from 1 to 21 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. The lens is indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less that does not interfere

with visual acuity. The lens ranges in powers from -10.00 diopters to +10.00 diopters.

CONTRAINDICATIONS

Hydrasoft XW contact lenses are contraindicated by the presence of any of the following conditions:

1. Acute and subacute inflammations of the anterior segment of the eye.
2. Any eye disease which affects the cornea or conjunctiva.
3. Insufficiency of lacrimal secretion.
4. Corneal hypoesthesia.
5. Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
6. Any active corneal infections; bacterial, fungal, viral, or purulent.
7. Allergy to any ingredient such as mercury or thimerosal in a solution which must be used to care for the lens.

ADVERSE REACTIONS

Serious corneal damage may result from wearing a lens which has been soaked in conventional hard lens solution. Eye irritation may occur within a short time after putting on a lens stored in a solution of improper pH or tonicity. Removal of the lens will relieve the irritation. Excessive tearing or redness, unusual eye secretions, reduced visual acuity, blurred vision, halos of light in the field of vision, and light sensitivity are not normal; if these symptoms occur, the patient should be examined by an eye-care practitioner to determine the cause.

WARNINGS

Medicaments and Eye Drops:

The Hydrasoft XW contact lens must be stored only in the recommended solutions. No ophthalmic solutions or medicaments should be used unless directed by your eye-care practitioner. Never use conventional hard contact lens solutions. Only the recommended disinfectant soaking solutions or cleaning solutions and rinsing solutions should be used. Lubricating solutions (see recommended list of solutions) may be used on the Hydrasoft XW contact lens.

Abrasions and Infections:

If the lens becomes less comfortable than when it was first placed on the cornea, or the vision becomes less clear, this may indicate the presence of a foreign body, an improperly cleaned lens or the lens may be in the incorrect eye. The lens should be removed immediately and examined. If any corneal abrasion, ulceration, irritation or infection is present, an eye-care practitioner should be consulted immediately.

Visual Blurring:

When visual blurring occurs, the lens must be removed and cleaned. If visual blurring continues, consult your eye-care practitioner immediately.

Wearing Restrictions:

The Hydrasoft XW contact lens should not be worn when swimming or in the presence of noxious and irritating vapors.

PRECAUTIONS

Lens Handling:

Patients must wash and rinse hands thoroughly and dry with a lint-free towel before handling the lenses. Cosmetics, lotions, soaps, and creams must not come into contact with the

lenses since eye irritation or lens discoloration may result. If hair spray is used while the lenses are being worn, the eyes must be kept closed until the spray has settled.

Fluorescein:

Never use fluorescein while wearing the lens because the lens will become discolored. Whenever fluorescein is used, flush the eyes with normal saline solution and wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual fluorescein irreversibly.

LENS CARE DIRECTIONS

Lens Care and Handling:

Patients must be supplied with lens care instructions and supplies. Regular post-fitting visits are necessary to assure patient health and compliance with instructions.

Storage:

Hydrasoft XW contact lenses must be stored only in the recommended solutions. If left exposed to air, the lenses will dehydrate. If a lens dehydrates, it should be soaked in the recommended storage solution a minimum of four hours.

Cleaning:

Removal for cleaning every three weeks is recommended. However, at the discretion of the eye-care practitioner, the lenses may be removed at a frequency adjusted to the needs of each patient. Each time the lenses are removed from the wearer's eyes, both surfaces of the lenses must be cleaned using several drops of the recommended cleaner.

Chemical Disinfection:

CHEMICAL DISINFECTION of the contact lens is necessary to remove potentially harmful microorganisms from the lens before

placing the lens on the eye. This can be accomplished by using the recommended solutions. Hydrasoft XW contact lenses must be cleaned and rinsed after wearing, with the recommended cleaning solution and saline rinse. The lens case must be emptied and refilled with fresh recommended storage disinfection solution prior to disinfecting the lenses. Fresh storage and disinfection solution must be used for storage and disinfecting the lenses.

WARNING: HEAT DISINFECTION SHOULD NOT BE USED WITH THE HYDRASOFT XW CONTACT LENS.

DOSAGE AND ADMINISTRATION

Fitting Information:

The eye-care practitioner will use conventional methods to fit the Hydrasoft XW contact lens for vision correction. For a detailed description of the fitting technique, refer to the appropriate hydrophilic contact lens professional fitting guide, copies of which are available from CoastVision, Inc., 18368 Enterprise Lane, Huntington Beach, California 92648.

Wearing Schedule:

Not every patient is able to wear a lens on an extended basis, even if able to wear the same lens on a daily basis. The eye-care practitioner should determine the wearing schedule. Periodic checkups by the eye-care practitioner are extremely important, especially for patients on an extended wear regimen. With extended-wear there may be increased risks of eye problems such as irritation, infection, corneal thickening and corneal ulcers.

HOW SUPPLIED

Each lens is supplied sterile in a glass vial containing

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sterile normal saline solution USP, buffered with sodium bicarbonate USP. The glass vial is marked with the base curve, dioptric power, diameter, manufacturing lot number, and expiration date of the lens.

To assure proper lens care and handling, each Hydrasoft XW patient MUST BE supplied with the Hydrasoft chemical disinfection patient care kit and the Hydrasoft XW Wearer's Guide. The recommended accessory products required for the chemical disinfection, cleaning and storage of Hydrasoft contact lenses consist of the following:

1. Cleaning - Preflex, Pliagel, Softmate Cleaner, or Allergan Cleaning and Disinfecting Solution.
2. Rinsing - Allergan Hydrocare Preserved Saline Solution, Unisol, or Prepared Unpreserved Normal Saline.
3. Disinfecting - Allergan Cleaning and Disinfecting Solution, Flexcare, or Softmate Disinfection and Storage Solution.
4. Lubricating Solutions - Adapettes or Clerz.

Caution: Federal Law prohibits dispensing without a prescription.

CoastVision, Inc.
18368 Enterprise Lane
Huntington Beach, California 92648

Printed 5/86

CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the Food and Drug Administration (FDA), Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Premarket Approval Application (PMA) Supplement. Before making any change that could affect the safety or effectiveness of the device, submit a PMA supplement for review and approval by Center for Devices and Radiological Health (CDRH). Such changes may include, but are not limited to:

- (1) new indications for use;
- (2) labeling changes;
- (3) changes in existing manufacturing facilities, methods or quality control procedures;
- (4) the use of a different facility or establishment to manufacture, process, or package the device;
- (5) changes in sterilization procedures;
- (6) changes in packaging;
- (7) changes in the performance or design specification, circuits, parts, components, accessories, ingredients, or physical layout of the device; and
- (8) extension of the expiration date of the device based on data obtained under a new or revised testing protocol that has not been approved by CDRH. If the protocol has been approved, the change shall be submitted along with the supporting data in the next periodic report required in the PMA approval order. An approved protocol is one included in FDA guidelines applicable to the device or in a PMA submission for the device for which the approval order granted the expiration dating requested by you. Otherwise, you must submit and obtain CDRH approval of a PMA supplement for an expiration dating protocol.

Changes described below that enhance the safety of the device or safety in the use of the device may be placed into effect before your receipt of a written FDA order approving the PMA supplement provided that:

- (1) the PMA supplement and its mailing cover are plainly marked "Special PMA Supplement - Changes Being Effectuated";
- (2) the PMA supplement provides a full explanation of the basis for the changes;
- (3) the applicant has received acknowledgment of FDA receipt of the PMA supplement;
- (4) the PMA supplement specifically identifies the date that such changes are being effectuated; and

(5) the changes are among the following:

- (a) labeling changes that add or strengthen a contraindication, warning, precaution, or adverse reaction or effect;
- (b) labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;
- (c) labeling changes that delete misleading, false, or unsupported indications; or
- (d) changes in the manufacturing process or quality controls that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength or reliability of the device.

You need submit only three (3) copies of a PMA supplement and include only information relevant to the proposed or effected changes in the device. The submission shall include a separate section that identifies all changes for which approval is being requested. You shall submit additional copies and additional information if requested by CDRH.

FDA may, as experience permits, issue guidelines listing specific types of changes that do not require FDA approval before implementation.

Post-Approval Reports. Continued approval of your device is contingent upon the submission of 2 copies of post-approval reports to the Food and Drug Administration, Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910 at intervals of 1 year from the date of this letter. The required contents of these reports will be described in the final order for the premarket approval procedural regulation which will be published in the FEDERAL REGISTER in the future. Until this regulation is published in final form, each periodic report shall consist of information that previously has not been submitted as part of a PMA supplement and which you have obtained since the last post-approval report or since receipt of this letter, whichever is later;

- (1) a bibliography and summary of reports in the scientific literature involving the device and unpublished reports of in vitro, animal and clinical experience studies, investigations, and tests conducted by, reported to, or reasonably available to you involving the device or a related device--if, after reviewing the bibliography and summary, CDRH concludes that it needs a copy of the published and unpublished reports, CDRH will notify you that copies of such reports shall be submitted;
- (2) written promotional material; and
- (3) a description of changes made in the device not previously submitted in a PMA supplement.

Adverse Reaction and Device Defect Reporting. You shall submit 3 copies of a written report to the Food and Drug Administration, Center for Devices and Radiological Health (CDRH), 8757 Georgia Avenue, Silver Spring, Maryland 20910 within 10 days after you receive or have knowledge of information about:

- (1) a mixup of the device or its labeling with another article;

- (2) any significant chemical, physical, or other change or deterioration in the device, or any failure of one or more of the the devices to meet the specifications established in the application;
- (3) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device; and
 - (a) has not been addressed by the device's labeling or
 - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

Reporting under the Medical Device Reporting (MDR) Regulation. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer, or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to reoccur.

The conditions of approval accompanying PMA approval orders may require that the same events subject to reporting under the MDR Regulation must also be included in periodic reports to the PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the conditions of approval for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Device Monitoring Branch (HFZ-343)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910
Telephone (301) 427-7500

Copies of the MDR Regulation and a FDA publication entitled, "An Overview of the Medical Device Reporting Regulation", are available by written request to the above address or by telephoning (301) 427-8100.

Note: All conditions of approval are subject to change upon publication of the final order for the premarket approval procedural regulation.