APR 16 1998

K974408

SAFETY AND EFFECTIVENESS SUMMARY

1.	**Name and address of submitter**	Biocompatibles Eyecare Inc. 1215 Boissevain Avenue Norfolk VA USA 23507 Contact Person: Lisa Hahn Telephone number: 800-225-3069 or 757-664-2421 Date summary prepared: 4/1/98
2.	**Identification of Device**	Trade Name: Proclear and Proclear Compatibles (omafilcon A) Soft Contact Lens Common or Usual Name: Soft (hydrophilic) Contact Lens (daily wear) Classification: Group II
3.	**Predicate Device**	Proclear (omafilcon A) Contact Lens

4. Description of Device

The Proclear and Proclear Compatibles contact lenses are available as a lathe cut spherical lens, and a molded spherical lens. The lens material (omafilcon A) is a copolymer of 2-hydroxyethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The Proclear lens with visibility tint is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling.

5. Intended Use (indications)

Proclear and Proclear Compatibles (omafilcon A) Soft Hydrophilic Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement.

6a Characteristics comparison of predicate to this device

Design, material, and chemical composition remain unchanged from those approved in Premarket 510(k) Notification's K952152, and K970095

6b 1. Non Clinical tests and results

Not performed; lenses remain unchanged from approved Premarket 510(k) Notification's listed above.

6b 2. Clinical Tests

The Safety and Effectiveness of the Proclear (omafilcon A) Soft Contact Lenses in Defined Dry Eye patients is demonstrated by the clinical result summarized here.

Dry Eye patients have been categorized in the Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes, published in the CLAO Journal, October 1995, Vol. 21, No. 4.

This study was undertaken to assess the Proclear lens in Defined Dry Eye subjects, who have a dry eye condition arising from Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

This prospective, randomized, controlled, crossover study was designed to assess the relative performance of the Proclear lens in 76 Dry Eye subjects as compared to their experience with the lenses with which they entered the study. It also addresses differences in signs and symptoms, lens preference, comfort and duration of continuous daily lens wearing time.

In Phase 1, the baseline against which the performance of the lens (Control or Test) is measured is the pre-study entry data. In Phase II, the baseline against which the lens is measured is the data at the crossover point in the study.

6b 3. Conclusions drawn from the studies

(Conclusions demonstrate device is safe, effective and performs as well as or better in the Defined population as in the population currently covered in the predicate approval)

Summary statistics are presented for selected variables. In the case of visual acuity and slit lamp findings, differences from baseline for each variable were calculated. These differences were compared pairwise between the lens types worn in each phase of the crossover trial at the given visits. With other variables, the actual values were compared in a similar pairwise fashion. The paired Student's t-test or Wilcoxon's signed ranks test for matched pairs were applied to normally distributed data and non-normal data respectively. In addition in the statistical analysis of the data from the Visual Analogue Scale, the Repeated Measures analysis method was used.

Adverse Reactions

There was only one adverse reaction involving severe injection in one eye at two weeks, of a subject who was wearing a Control lens. The problem was attributed to tight lens syndrome. The subject was discontinued.

7. Conclusion

The differences noted between the experience of Proclear and Control lens wear, by study Phase, supports the premise that on entry to the clinical trial, an improvement over baseline measures is gained as a function of a change to fresh lenses. It also supports the premise that the magnitude of beneficial change is greater for the Proclear lens wearing subjects in Phase 1. On crossover, the premise was that the beneficial effect achieved through Proclear lens wear in Phase 1 might be diminished or lost by use of Control lenses in Phase 2. Conversely, the beneficial effect, gained from use of fresh Control lenses in Phase 1, were expected to be manifest in the early interval(s), but possibly erode thereafter. On crossover to Proclear use

in Phase 2, any beneficial effect in Phase 1 was projected to be sustained or further enhanced. As discussed above, validity of this premise has been demonstrated.

8. Comparison of Proclear and Proclear Compatibles Performance in defined Dry Eyes Vs. Normal, Eyes : 510(k) Reference K970095 FDA Tables 1-11

The Definition of success for the comparison to the performance of Proclear in a Normal Vs. Defined Dry Eye population is provided below:

Improvement or no significant difference in visual acuity; slit lamp findings; symptoms, problems, and complaints; or Adverse Reactions as compared to the performance of the lens in the Normal eye population.

The Proclear and Proclear Compatibles lens performs in an equivalent manner in Normal and Dry Eyes except for the parameter of Average Wearing Time. However, the Proclear lens had a statistically significant greater Average Wearing Time in Dry Eyes (clinical relevance of this difference has not been established) than was reported for the Control lenses in the Dry Eye Population, as assessed in the Matched Pairs analysis.

9. Further basis for modification in indication for use to permit inclusion of Defined Dry Eye subjects

Resistance to On-eye Dehydration

The data indicated that the Relative Dehydration for the Proclear lenses in Dry Eyes was consistently low as compared to that reported for the population of Control lenses in Dry Eyes p=0.0001. The Matched Pair analysis confirms that the hydration retention characteristic of the Omafilcon A material in the Proclear lens is significantly more resistant to on-eye dehydration than the control lenses.The lenses in the study ranged in power from -9.00 to + 6.00 D, encompassing center thicknesses of 0.07 mm to 0.31 mm. Not every quarter diopter power was represented in the study, therefore individual patient on-eye dehydration response may vary.

Signs and Symptoms Analysis: Visual Analogue Scale Method Results

The Subjects were required to provide their Self-evaluation of Symptoms Problems and Complaints on a Visual Analogue Scale (VAS) at each post-fit interval. These data have been analyzed in three ways:

a. Graph of Mean Scores for the Proclear and Control Populations, as a function of study Phase
b. Frequency Distribution of Change from Baseline for the Proclear and Control populations, as a function of study Phase
c. Performance Comparison in Phase 1 and Effect of Phase 1 Lens Used on performance in Phase 2

PERFORMANCE OF THE OMAFILCON A LENS DEFINED DRY EYE SUBJECTS RELATIVE TO THE DEFINITION OF SUCCESS

Success for the Proclear lens in dry eye subjects was defined as the following:

A. A statistically significantly difference in the On-eye hydration retention relative to the Control lenses in Matched Pair Analysis.

This has been demonstrated in the analysis found above.

B. Achievement of a statistically significant increase in wearing time over baseline and/or the Control lens.

The omafilcon A lenses had statistically significantly longer wearing times at each intervals, determined using the Wilcoxon's Test for Matched Pairs.

C. Improvement or no significant difference in visual acuity; slit lamp findings; symptoms, problems, and complaints; or Adverse Reactions as compared to the performance of the Control lens in the same population.

On the FDA defined comparative parameters, the omafilcon A lenses performed in an equivalent manner to the Control lenses except for the parameters of Wearing Time, as discussed above, and the various Symptoms, Problems and Complaints (SPCs). This difference is explored more fully in the Signs and Symptoms analysis using the VAS method, as discussed in the Statistical Analysis section below.

D. A significant difference in Signs and Symptoms relative to the Control lenses.

A review of the data confirms that this premise is valid on each of the parameters. Of greatest interest are the differences seen on the parameters of Comfort, Moistness of the Eye and the Frequency of Dry Eye Symptoms. The results for Comfort are further supported by the differences on the various parameters, which detail Comfort: irritation, itchiness, burning, grittiness, watering, light-sensitivity, variation in eye sensations throughout the day, and noticeability.

Statistical Analysis

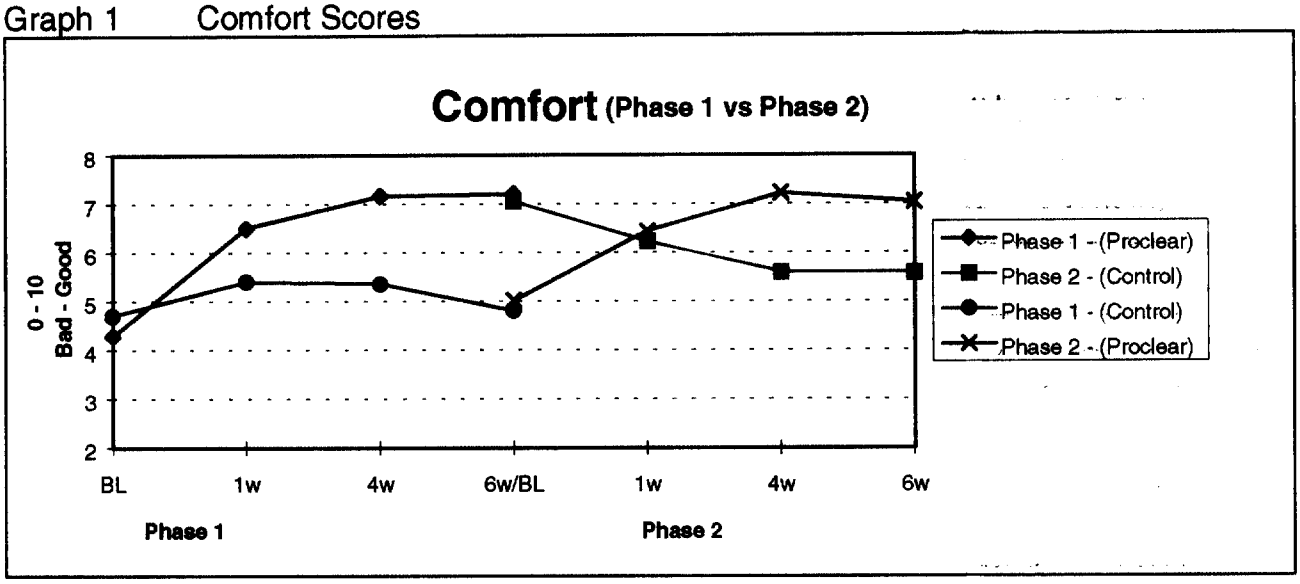
Repeated Measures Analysis indicates significant differences in favor of Proclear at all intervals for the parameters of Lens Comfort. The elements of comfort were significantly better for the omafilcon A lenses in each study Phase as determined with the Repeated Measures Analysis for the Dry Eye population.

Matched Pair Analysis indicates significant differences in favor of omafilcon A lenses at all intervals for the parameter of Comfort, Moistness of Eye, Frequency of Dryness symptoms, Frequency of Itchiness symptoms, Frequency of Soreness, Frequency of Scratchiness symptoms, Frequency of Grittiness symptoms, and Frequency of Light Sensitivity.

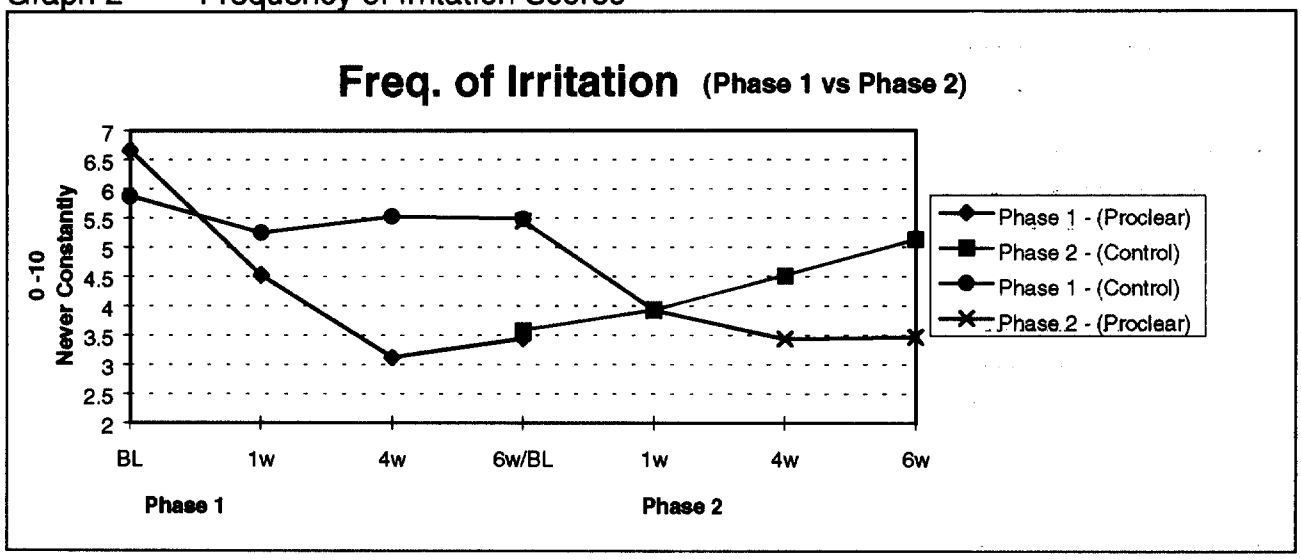
Chi Squares Test (Analysis of the Frequency Distribution of change from baseline) identified significant differences in favor of omafilcon A lens at each interval on the parameters of: Lens Comfort, Moistness of Eye, Frequency of Dryness Symptoms Noticeability (just noticeable/unbearable), Frequency of scratchiness, and Frequency of Itchiness.

Overall, the subjects wearing omafilcon A lenses reported improved lens performance to that reported for the Control lenses, with the differences in performance becoming more marked as the period of post-fit time increased. Graphs showing the performance of these subjective parameters were plotted for both the Proclear and the Control lenses. The graphs clearly depict the greater degree of improvement in performance of the Proclear Vs Control lenses in Dry Eyes. The frequency distribution of the change from baseline for each of these parameters further details the specific differences between the two populations.

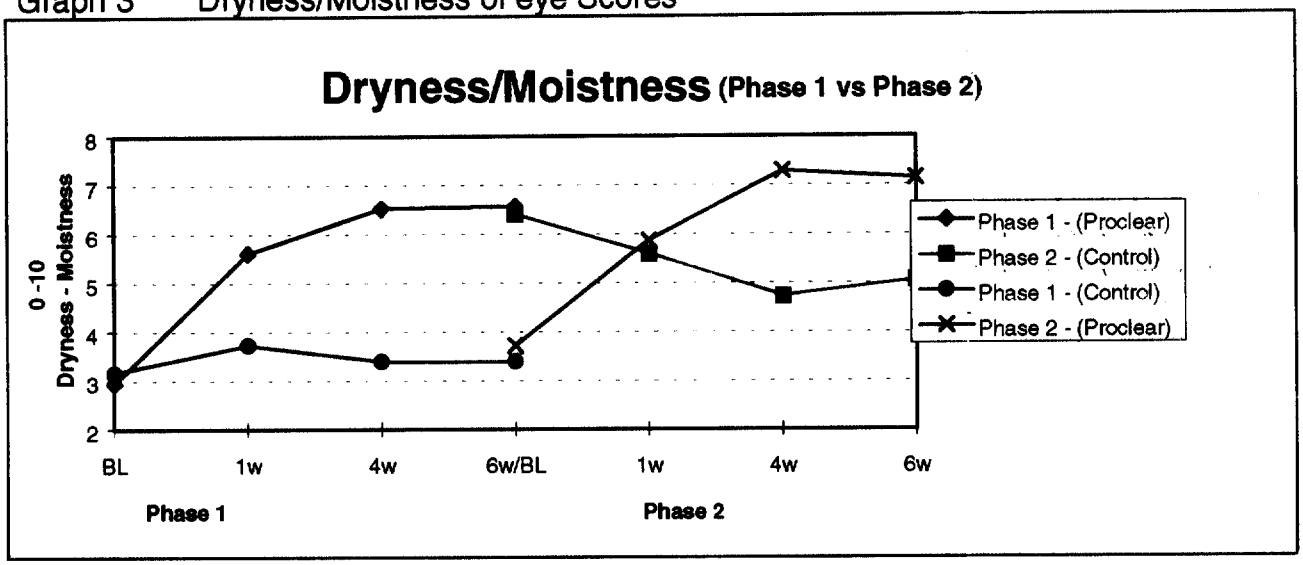
Graph 1 Comfort Scores



Graph 2 Frequency of Irritation Scores



Graph 3 Dryness/Moistness of eye Scores



Graph 4 Frequency that Eyes Feel Dry Scores

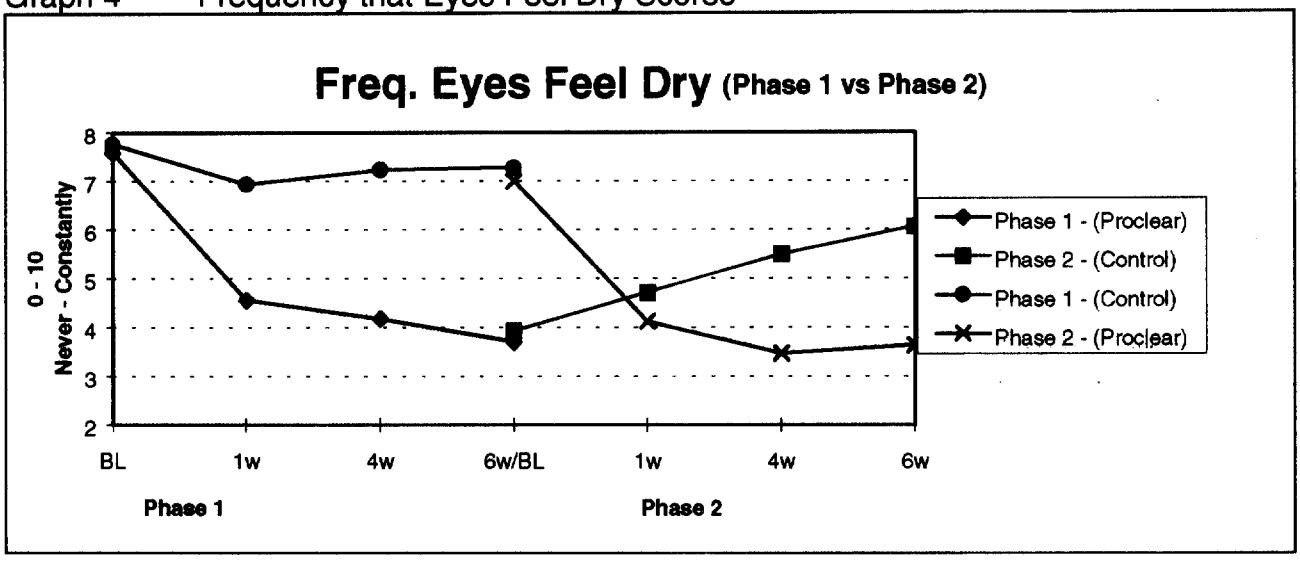


Table 1 Water Content Results by Lens Material Type

		Group 1		Group 2		Group 4	
Material		Proclear	Control	Proclear	Control	Proclear	Control
Number of Eyes		28	23	8	6	42	44
Baseline Water Content (%)	Mean	61.0	40.9	60.0	68.4	61.2	57.1
	SD	1.07	6.45	1.07	7.36	0.94	6.73
Water Content 6 Weeks (%)	Mean	60.0	40.1	60.1	65.5	60.2	53.1
	SD	1.56	7.15	1.48	5.86	1.63	6.65
Absolute difference of Water Content at 6 Weeks (%)	Mean	1.36	1.80	1.63	2.92	1.49**	3.99
	SD	1.54	1.61	1.22	1.69	1.58	3.81
Relative Dehydration at 6 Weeks (%)	Mean	2.21**	4.65	2.65	4.09	2.41**	6.78
	SD	2.46	4.15	1.98	1.69	2.54	6.34

The lenses in the study ranged in power from -9.00 to + 6.00 D, encompassing center thicknesses of 0.07 mm to 0.31 mm. Not every quarter diopter power was represented in the study, therefore individual patient on-eye dehydration response may vary.

N.B. No measurements were completed for lenses from Group 3 due to insufficient lenses for statistical analysis..

Asterisks indicate significant differences : * $p \leq 0.05$, ** $p \leq 0.001$

Control Lenses used in above Groups are:

Group 1 - Low water content (<50%), Nonionic

Group 2 - High water content (≥50%), Nonionic

Group 4 - High water content (≥50%), Ionic

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1998

Ms. Lisa Hahn
Director of Regulatory Affairs
Biocompatibles Eyecare, Inc.
1215 Boissevain Avenue
Norfolk, VA 23507

Re: K974408
Trade Name: Proclear and Proclear Compatibles (Omafilcon A) Soft Contact Lenses for Daily Wear
Regulatory Class: Class II
Product Code: 86 LPL
Dated: March 9, 1998
Received: March 10, 1998

Dear Ms. Hahn:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597.

Sincerely yours,

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

Enclosure

510(K) Number : K974408

Device Name: Proclear and Proclear Compatibles(omafilcon A) Daily Wear Contact Lens

Indication for use:

Proclear or Proclear Compatibles :

(omafilcon A) Soft Hydrophilic Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

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

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K974408

Prescription Use ✓ OR Over the counter use _____

(Optional format 1-2-96)