

JUN - 6 2000

510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K991206

1. Submitter's Identification:

Sponsor:

Bonasse Enterprises Company, Ltd.
No. 7 Lane 16 Yuon-An South Rd., Sec. 2
Luchou City, Taipei, Taiwan

Submitted by:

Carolann Kotula
mdi Consultants
Phone: 770-985-8293
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Date Summary Prepared: May 30, 2000

2. Name of the Device:

The subject devices for this submission are the following:

Bonasse Flat Bed Soaking case, Model SC 106
White case and caps

Bonasse Non-Vented Barrel Style Contact Lens Case.
Models BC 760-1-2-3; BC-793.
White cap, lens holder, lens basket
Clear Barrel

3. Predicate Device Information:

The Bonasse Contact Lens cases are substantially equivalent in design, materials, and intended use to the Alcon Opti-Free contact lens case.

4. Device Description:

The Bonasse contact lens cases are molded plastic, flat or barrel style cases with screw top lids, similar in design to currently marketed products. The barrel styles include a lens basket used for holding the lens during storage.

5. Intended Use:

The Bonasse Flat Bed and non-vented barrel style of Contact Lens Cases are For storage of soft (hydrophilic), rigid gas permeable (RGP), and hard contact lenses during chemical disinfection.

6. Comparison to Predicate Device:

	Alcon Opti-Free Contact Lens Case	Bonasse Flat Bed Soaking Case	Bonasse Non Vented Barrel Case
Intended Use	Storage and chemical disinfection	Storage and chemical disinfection	Storage and chemical disinfection
Materials	Similar	Similar	Similar to Ciba Vision disposable cup (see below)
Design	Similar Flat bed case with screw on caps. R/L embossed on caps. R/L cap contrasting colors Non-vented caps	Similar Flat bed case with screw on caps. R/L embossed on caps. R/L cap same color Non-vented caps.	Similar Clear Barrel, White (screw on) cap; lens holder, lens basket. R/L marked on lens baskets. Non-vented cap
Labeling	Similar	Similar	Similar, extra precautions added

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:**

Biocompatibility testing by a third party laboratory demonstrated the materials are safe for use in contact lens storage and disinfection.

8. **Discussion of Clinical Tests Performed:**

No clinical test were performed

9. **Conclusions:**

The Bonasse Contact Lens cases are safe and effective for their intended use.



JUN - 6 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bonasse Enterprise Co., Ltd.
c/o Ms. Carolann Kotula
MDI Consultants, Inc.
55 Northern Blvd.
Great Neck, NY 11021

Re: K991206

Trade Name: Bonasse Flat Bed Soaking Case
Model SC 106 (white: case and caps)
Bonasse Non-Vented Barrel Style Contact Lens Case
Models BC 780-1-2-3; BC-793 (white: cap, lens holder, and lens basket; clear:
barrel)

Regulatory Class: Unclassified
Product Code: 86 LRX
Dated: April 21, 2000
Received: April 25, 2000

Dear Mr. Beneke:

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.

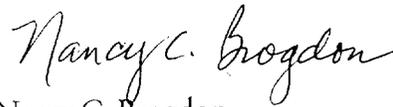
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Ralph H. Larsen

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) 594-6413. 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 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/dsma/dsmamain.html>".

Sincerely yours,



Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K991206

Device Name: Bonasse Flat Bed Soaking case, Model SC 106
White caps and case

Bonasse Non-Vented Barrel Style Contact Lens Case.
Models BC 760-1-2-3, BC-793.
White cap, lens holder, lens basket
Clear barrel

Indications for Use:

For storage of soft (hydrophilic), rigid gas permeable (RGP), and hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Not to be used with 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)

M. J. Owen Shurt

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K 99 1206

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

(Optional Format 1-2-96)