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SUSAN L. JOHNSON
Chief Executive Officer
susan@ardenlabs.com

ANGELA STRANTZ, Ph.D.
Chief Technical Officer
angela@ardenlabs.com

K024079

510(k) Summary

Submitted by:	Arden Laboratories, Inc. 468B Stillwater Road P.O. Box 486 Willernie, Minnesota 55090-0468 Telephone 651-762-9224 Fax 651-762-9226 E-mail angela@ardenlabs.com
Contact:	Angela Strantz, PhD Chief Technical Officer
Prepared on:	December 6, 2002
Trade Name:	ALIBI Biological Indicator
Common Name:	Biological Indicator for Ethylene Oxide, Paper Carrier
Classification:	II
Predicate Device:	Raven Bacterial Spore Strip Pre-amendment device
Description:	ALIBI is a biological indicator that complies with the USP XXV:2002 monograph *Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.* The ALIBI biological indicator consists of a paper carrier inoculated with of *Bacillus subtilis* var. *niger* ATCC 9372 bacterial endospores, and a primary package made of glassine. After exposure to an ethylene oxide sterilization cycle, the biological indicator is incubated in soybean casein digest broth at 30-35°C for 7 days.

P.O. Box 687 • 468B Stillwater Road • Willernie, MN 55090-0687 • 651.762.9224 • Fax 651.762.9226

Description (continues):	Growth of biological indicator spores is evidenced by the presence of turbidity in the growth medium. If the sterilization cycle killed all of the biological indicator spores, the growth medium remains clear.
Intended use:	The ALIBI biological indicator is used to monitor the efficacy of ethylene oxide sterilization cycles.
Statement of Similarity:	Equivalence of the ALIBI biological indicator is demonstrated through compliance to the recognized standard, USP XXV:2002 monograph *Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.*
Description of Testing	Stability studies on three lots manufactured from three different spore crops are in progress. Each lot is evaluated for population, purity, D_{EO}-value, survival time and kill time. The methods described in USP XXV were used, except for the population test. Here a validated, alternative method is used. Real time data through the 12 months test interval shows that population, purity, and resistance values remain within the acceptance criteria in USP XXV.
Conclusion:	The ALIBI biological indicator is appropriate for monitoring the efficacy of ethylene oxide sterilization cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Angela Strantz
Chief Technical Officer
Arden Laboratories, Incorporated
468B Stillwater Road
Willernie, Minnesota 55090

Re: K024079
Trade/Device Name: The ALIBI Biological Indicator
Regulation Number: 880.2800 (a)
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: December 6, 2002
Received: December 10, 2002

Dear Dr. Strantz:

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.

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) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: ALIBI Biological Indicator

Indications for Use:

The ALIBI biological indicator is used to monitor the efficacy of ethylene oxide sterilization cycles.

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K024079