AUG 2 9 2003

K032526

1. 510(k) Summary (in accordance to 21 CFR 807.92)

Submitted by: Dr. Paul Distler (Product Manager)
BINDER GmbH
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Date: May 13, 2003

Names of Devices:

Trade Name:	Binder CO_2 incubator series CB (CB 150-UL and CB 210-UL)
Common/Usual Name:	CO_2 Incubator / Embryo Incubator
Classification Name:	CO_2 Incubator / Embryo Incubator 21 CFR 884.6120

Predicate Device: Forma Scientific Universal Water Jacked Incubator (ThermoQuest Corp.)
Reference No. K991408, cleared 07/19/1999

Device description:
BINDER incubators series CB are bench top or floor standing units. There are two different sizes available. One of approximately 5.3 cubic feet inner volume (150 liters) and one with 7.4 cubic feet volume (210 liters). One multi-channel controller with a large area LCD screen controls the growth parameters temperature and inner carbon-dioxide (CO_2) concentration and provide elevated humidity. The inner chamber volume is closed against the environment. Optionally the units are equipped with a control channel for Oxygen (O_2).Temperature, CO_2 concentration (optional also O_2 concentration) are microprocessor controlled. Constant and reliable temperatures are achieved by the patented air-jacked heating system. The air-jacket provides highly precise and homogeneous temperatures within the incubator which is ideal for long term culturing. The system has very short recovery times upon door openings. The concentration of CO_2 is controlled by a single beam infrared (IR) difference detector. The IR sensor has an auto correction function and is characterized by minimal reaction latencies. The detection system for the optional Oxygen control bases on the amperometric system of a Zirconium-Dioxide (ZrO_2) electrode.
The incubator is equipped with a dry-heat decontamination function at 187°C (368.6°F).

Intended Use:
Incubators series CB provide suitable growth-conditions for $NaHCO_3$ -buffered cell cultures of ova or embryos with controlled temperature at or near 37°C (98.6°F) and carbon-dioxide atmosphere (optional additionally at hyper oxide or hypo oxide atmosphere) at a high humidity. A automatic dry heat decontamination process of the empty incubator, applicable between different loadings assists to avoid contaminations of the cell cultures.

Comparison to predicate device:
The two incubators are very similar except that the BINDER incubator has an air-jacket heating system that allows to proceed a dry-heat decontamination at 187 °C (368.6°F) of the inner chamber and the interior equipment whereas the Forma incubator is equipped with a water jacket and no decontamination facility.

Discussion of non clinical tests:
The BINDER incubator passed through tests for electrical safety, electromagnetic compatibility testing, operating performance testing and decontamination testing successfully.

Discussion of clinical tests: not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Ms. Pamela Gwynn
Engineering Team Leader
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K032526
Trade/Device Name: BINDER CO_2 incubator series CB
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: 85 MQG
Dated: July 21, 2003
Received: August 15, 2003

Dear Ms. Gwynn:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3-3 Indication for Use Statement

Ver/ 3 - 4/24/96

Applicant: BINDER GmbH

510(k) Number (if known): K032526

Device Name: BINDER CO_2 incubator series CB

Indications For Use:

Incubators series CB provide suitable growth-conditions for NaHCO3 -buffered cell cultures of ova or embryos with controlled temperature at or near 37°C (98.6°F) and carbon-dioxide atmosphere (optional additionally at hyper oxide or hypo oxide atmosphere) at a high humidity. An automatic dry heat decontamination process of the empty incubator, applicable between different loadings assists to avoid contaminations of the cell cultures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032526

Prescription Use √