

JAN 24 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

510 (k) Submission K99 1618

Propper BI – O.K.™ Self-Contained Biological Indicator
(for use in steam autoclaves)

General Information:

Submitter's Name/Address

Propper Manufacturing Company Inc.
36-04 Skillman Avenue
Long Island City, NY 11101
Attn: John D. Dyckman Ph.D.

Common Name of the Device:

Biological/Chemical Indicator

Trade Name of the Device:

BI-O.K.

Classification Information:

Class II, Sterilization Process Indicator

Indications for Use:

The Propper BI-O.K. steam biological indicator is indicated for use in testing both gravity displacement steam sterilizers at 121°C and prevacuum steam sterilizers at 134°C.

Device Description:

The Propper BI-O.K. self contained steam biological indicator consists of a plastic vial and cap which contain a paper strip impregnated with a known number of B. steothermophilus spores and a sterile sealed glass ampule containing a modified

Soybean Casein Digest Medium with pH indicator. Following exposure in a steam sterilizer, the glass ampule is crushed by squeezing the sides of the plastic vial , thus bringing the medium into contact with the spores. The vial is incubated at $56 \pm 2^{\circ}\text{C}$ for at least 24 hours. If any of the spores survived the sterilization process, they will grow and produce acid. This will cause a drop in pH of the medium and change the indicator from red to yellow.

Substantial Equivalence:

The Propper BI-O.K. Self Contained Steam Biological Indicator has been patterned from the same materials, size, and construction as a biological indicator which has been on the market for over 20 years as well as one that has been marketed for over five years. It has a spore population and D value which are in the range of other products of this type on the market. The instructions for use and handling are typical for indicators of this type.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2001

Mr. John D. Dyckman
Vice President of Product Research
Propper Manufacturing company, Incorporated
36-04 Skillman Avenue
Long Island City, New York 11101

Re: K991618
Trade Name: BI-O.K. Self-Contained Biological Indicator
Regulatory Class: II
Product Code: FRC
Dated: October 26, 2000
Received: October 26, 2000

Dear Mr. Dyckman:

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 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). 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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

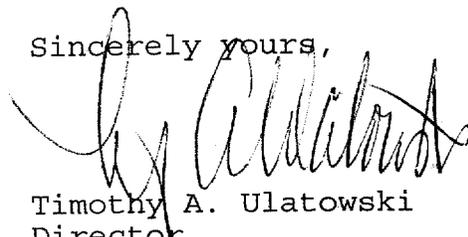
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Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

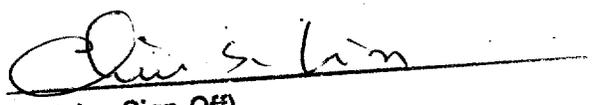
Device Name: BI-O.K.™

Indications For Use:

The Proper BI-O.K. steam biological indicator is indicated for use in testing both gravity displacement steam sterilizers at 121°C and prevacuum steam sterilizers at 134°C.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K991618

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

Section 807.87 (a)

(Optional Format 1-2-96)