



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

March 26, 2013

Ms. Jole Wilson  
Quality Assurance Manager  
Bozeman Manufacturing Facility  
10 Evergreen Drive  
BOZEMAN, MONTANA 59715

Re: K122362  
Trade/Device Name: Smart-Well Model 1710 EZTest Incubator  
Regulation Number: 21 CFR 880.2800  
Regulation Name: Sterilization Process Indicator  
Regulatory Class: FRC  
Product Code: II  
Dated: February 25, 2013  
Received: February 26, 2013

Dear Ms. Wilson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Anthony D.  
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Watson - S 2013.03.26  
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Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**002\_Indications for Use Statement**

**510(k) Number** K122362

**Device Name** Smart-Well Model 1710 EZTest Incubator

**Indications for Use**

The Smart-Well Model 1710 EZTest Incubator is intended for use with the Smart-Read EZTest Steam self-contained biological indicator (SCBI).

When an activated Smart-Read EZTest Steam SCBI is placed into one of the incubation cavities the LED in front of the cavity will illuminate amber, which indicates that the incubator electronically recognizes the Smart-Read EZTest Steam SCBI unit for incubation.

Smart-Read EZTest is a Self-contained Biological Indicator (SCBI) intended for use in determining the efficacy of steam sterilization processes. The SCBI may be used in the following steam sterilization cycles:

Cycle Type	Cycle Temperature	Cycle Exposure Time
Gravity	121°C	30 minutes
Gravity	132°C	10 minutes
Flash Gravity	132°C	3 minutes*
Pre-Vac	132°C	4 minutes
Pre-Vac	135°C	3 minutes

\*Unwrapped nonporous devices only.

Each incubation cavity also has an electronic monitoring system that detects if the BI is either purple or yellow.

The Smart-Well Model 1710 EZTest Incubator can also be supplied with a printer which documents each individual Smart-Read EZTest Steam SCBI tested. The printer can also display information that is normally manually entered into a log book. The printer can also be configured to display BI exposure information that includes BI Lot number, Sterilizer number, User identification and Cycle ID. If no selection is made for these options during the BI Wizard set up, the printed report will print a "?" mark indicating no selection was made.

The printed record will always indicate incubation cavity being reported, BI results (status), incubation start date and time when the SCBI was placed into the incubation cavity and the total time of incubation. The result options are 1) NEGATIVE (purple)—incubation time completed with no detectable color change in the Smart-Read EZTest unit, 2) POSITIVE (yellow)—time that a yellow color was detected in the Smart-Read EZTest unit, or 3) TESTING—when a printout is requested and event 1) or 2) have not happened. These results are easily verified by the user as performed in all conventional incubators without printers.

Prescription Use \_\_\_\_\_ or Over-the-Counter Use  X

**PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie   
2013.03.26 11:18:19 -04'00'

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: \_\_\_\_\_