

510(k) Summary

K962903

(1) Submitter:

MAR - 3 1998

Prestige Medical
P.O. Box 154
Off Clarendon Road
Blackburn, Lancashire BB1 9UG
United Kingdom

Contact Person: Robert N. Stevenson

Date Summary Prepared: February 20, 1998

(2) Device Proprietary Name: Prestige Medical Series 2100 Clinical Autoclave

Common Name: autoclave

Classification Name: steam sterilizer

(3) Predicates: KaVoKlave Steam Autoclave, K910789
#M8 Electronic Sterilizer, K900432

(4) Device Description: The Series 2100 clinical autoclaves by Prestige Medical are Model numbers 2100 07 (extended body) and 2100 06 (standard body). Both are 120 volt autoclaves, which have a 18 minute sterilization cycle at 121°C. The height of the extended body autoclave is slightly greater than that of the standard body (420mm versus 335mm).

(5) Intended Use: The autoclaves are intended to sterilize unwrapped solid instruments (*i.e.*, excluding lumened instruments and dental handpieces) and non-porous loads at cycle parameters of 121°C saturated steam process for 18 minutes.

(6) The devices have substantially the same technological characteristics as the devices cleared under K910789 and K900432, and the identical materials, design, composition and function as the products currently marketed under K910789 and K900432. The slight modification reflected in the subject devices is that the "plug and pintle," which performed air bleed, pressure indicator and excess pressure relief functions, has been replaced by three separate components, each of which fulfills one of the functions formerly performed by the plug and pintle. The three separate components are: an air bleed device; a pressure rise indicator in the lid of the product; and a gasket blow-out slot through which a sealing gasket may extrude if necessary.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1998

Mr. Mark A. Heller
Prestige Medical
C/O Hale and Dorr LLP
1455 Pennsylvania Avenue, N.W.
Washington, DC 20004

Re: K962903
Trade Name: Prestige Medical Series 2100 Clinical
Autoclave
Regulatory Class: II
Product Code: FLE
Dated: December 23, 1997
Received: December 23, 1997

Dear Mr. Heller:

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 (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 requirement, 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

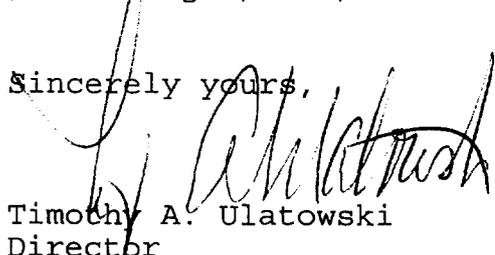
Page 2 - Mr. Heller

through 542 of the Act for devices under the Electronic 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) 594-4618. 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" (21 CFR 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/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): K962903

Device Name: Prestige Medical Series 2100 Clinical Autoclaves

Indications for Use:

The Models 2100 06 and 2100 07 Clinical Autoclaves are intended to sterilize unwrapped solid instruments (i.e., excluding lumened instruments and dental handpieces) and non-porous loads at cycle parameters of 121° Celsius saturated steam process for 18 minutes

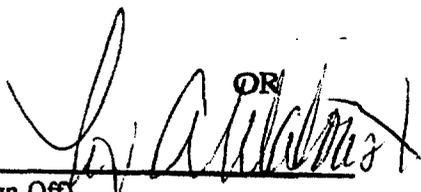
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use X


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

510(k) Number K962903

(Optional Format 1-2-96)