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K953938

510(k) Safety and Effectiveness Summary

Manufacturer:

Barnstead/Thermolyne Corporation
2555 Kerper Boulevard
Dubuque, Iowa 52001
Phone (319) 556-2241 Fax (319) 556-0695

Contact Name: Craig Case, Product Manager

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Common Name: Autoclave, table top steam Sterilizer

Trade Name: "Sterilemax"

Classification Name: Steam Sterilizer (per 21 CFR 880.6880)
(size category less than two cubic feet)

Substantial Equivalence:

The B/T (Barnstead/Thermolyne) "Sterilemax" is claimed to be substantially equivalent in safety and effectiveness to the following two steam sterilizers currently approved and legally marketed; the Tuttenauer American Gold - 510(k) No. K833837 and the MDT S-8 - 510(k) No. K910777.

General Description:

The B/T "Sterilemax" is a table top steam sterilizer. As in the case of the predicate units, the Sterilemax has a water reservoir, a heat source and a sealed chamber.

The unit is designed with four standard cycles and one optional cycle. The standard cycles are: wrapped instruments (10 min at 135 C.), unwrapped instruments (3 min at 135 C), packs (30 minutes at 121 C.), the optional cycle for dental handpieces (10 min at 132 C.) and liquids for non-clinical applications (15 min at 121 C.).

Design and Materials:

The chamber is constructed of stainless steel with a cast aluminum door and a silicone sealing gasket. The pressure chamber and components are designed, tested and stamped for conformance to ASME code.

A microprocessor controls the cycle parameters. The software provides the microprocessor with the necessary information to control the process per the programmed parameters. The software has been validated and documented under the requirements outlined in the "Reviewer Guide for Computer Controlled Medical Devices."

Intended Use:

The "Sterilemax" provides sterilization of standard loads of

medical and dental instruments, as do the predicate units.

Technology Considerations:

The unit has an 80 character alpha-numeric display. This display provides program and process information to the user, as well as fault condition messages. The display also provides the user with instructions regarding device operation.

The unit meets the requirements of UL/CUL3101-1, IEC 1010-1-92 safety standards. The unit is designed with additional user safety features such as, door interlocks and over temperature controls.

The chamber is 12" diameter by 18" deep. This chamber is somewhat larger than the predicate units. The general construction and operation is similar to the claimed predicate units.

Safety and Effectiveness:

Evaluations have been completed to validate the safety and effectiveness of the unit. The plan for this testing was derived from AAMI and accepted industry standards. Validation testing was performed using the half cycle analysis and total kill endpoint for each of the four standard cycles and the optional cycle for dental handpieces. The unit rendered all recommended loads sterile on half cycles.

The liquid cycle is not recommended for clinical applications.

Conclusion:

It is the conclusion of Barnstead/Thermolyne that the Sterilemax is substantially equivalent to the predicate devices; the Tuttenauer American Gold - 510(k) No. K833837 and the MDT S-8 - 510(k) No. K910777. Based on the test data submitted the Sterilemax provides effective sterilization of recommended loads with recommended cycles.