**Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities (Text Only)**

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DATE:     September 19, 1995

FROM:     Acting Director, Pilot Division, DDIG (HFZ-420)\_\_\_\_

SUBJECT: Addendum to the Sterilizer Guidance Document

TO:       DSMA

The purpose of this memo is to amend the "Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities, dated March 1993, to provide the following:

1.   clarification of the types of test data required for steam and dry-heat sterilizers with sterilization cycle parameters which differ from the traditional sterilization cycle parameters (e.g., for steam, temperatures other than 121o and 132o C; and for dry heat, 160o and 190o C);

2.   clarification of simulated-use and in-use testing requirements for traditional sterilizers; and

3.   clarification of the types of organic loads which are acceptable for simulated use performance testing.

Steam and Dry-Heat Sterilizers with Sterilization Cycle Parameters Which Differ From the Traditional Sterilization Cycle Parameters:

FDA has received 510(k) submissions for steam and dry heat sterilizers, especially table top steam sterilizers, describing new cycle parameters which differ from the traditional cycle parameters of preamendment or previously cleared steam and dry heat sterilizers. Usually the descriptions of the cycles suggest higher operating temperatures for steam and dry heat cycles and, in addition, higher pressures for steam cycles. The information in these submissions is usually not sufficient to describe the proposed new cycles in the following areas:

1.   The resistance and performance characteristics of the biological indicators, which were used to validate these new sterilization cycles, have not been established at the proposed temperatures and pressures.

2.   The performance characteristics of sterilization wraps and process indicator strips, such as pass-through indicators, have not been established for the proposed cycles.

3.   There is a lack of information on material compatibility and device functionality after repeated exposures to the proposed cycles.

4.   No information has been provided to the user on the appropriate selection of biological indicators, sterilization wraps, or process indicator strips for monitoring or for use in the proposed cycles.

The above information is available for the traditional steam and dry heat sterilization cycles. Therefore, the following, with supporting data, must be provided in the submissions for these new/non-traditional cycles before a decision regarding substantial equivalency can be made:

1.   The biological indicators must be validated for use with these new/non-traditional cycles. At a minimum, validation of biological indicators must include D-values and survival/kill characteristics at the proposed operating temperatures and pressures. Methods for validating the performance of the biological indicators have been described in the United States Pharmacopeia, the Parental Drug Association, ANSI/AAMI/ISO standards, and the CDRH checklist for biological indicators.

2.   The performance of the process indicator strips for use with proposed cycles must be validated and the performance characteristics of the strips (i.e., time, temperature, color change specifications, etc.) at the proposed cycle parameters must be described.

3.   The effect of the new/non-traditional proposed cycles on sterilization wraps must be evaluated. Any limitations or contra-indications regarding the wraps must be included in the Instructions for Use for the sterilizer.

4.   The effect of repeated exposures to the higher temperatures and pressures (as applicable) on material and/or device functionality must be evaluated. Any limitations must be included in the Instructions for Use for the sterilizer.

5.   A substantial equivalency determination for the sterilizer will be contingent upon substantial equivalency determinations for the biological indicator, sterilization wrap, and process strip indicator, etc., at the proposed operating temperatures and pressures.

Simulated-use and In-use Testing Requirements for Traditional Sterilizers

As indicated in the sterilizer guidance document, simulated-use and in-use testing are normally not required for traditional sterilizers with cycle parameters such as those listed in item No. 1 above. However, if any of the following conditions are present, results from simulated-use and in-use

testing must be included in 510(k) submission:

     a.   claims for complex lumened devices, such as dental handpieces; or

     b.   new sterilization parameters which differ from the traditional sterilization cycle parameters (e.g., for steam, temperatures other than 121o and 132o C; and for dry heat, temperatures other than 160o

          and 190o C);

Please note that other conditions may be added to the above list as warranted.

Because of the design features of the lumened devices and the unique limitations of the various sterilization parameters, data based upon physical testing and microbiological efficacy testing as described in Sections L and M of the sterilizer guidance document may not be sufficient to support the sterilization claims and additional testing may be necessary.

Recommendations for Organic Load Requirements for Simulated-use Test Protocols

The March 1993 guidance for sterilizers used in healthcare settings recommends that an artificial soil be used in the simulated-use tests. 5% serum and AOAC defined hard water are listed as examples of organic and inorganic loads which can be used as artificial soils. However, 5% serum and AOAC defined hard water may not be the appropriate challenge for all types of sterilization technologies. The type of organic challenge used in the simulated-use testing must represent a serious challenge to the sterilization technology. Therefore, the manufacturer will be asked to justify that the selection of the artificial soil represents a significant challenge to the sterilization process and is representative of the types of organic loads to which the devices would be exposed during actual use conditions. The AAMI TIR No. 12-1994, "Designing, Testing, & Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers"  identifies examples of artificial soils which may be suitable as challenge to the sterilization process. The TIR indicates that Hucker's Soil was formulated to simulate fecal material. Another example of simulated fecal material, described by R. S. Miles in J. Hospital Infection (1991) 18 (Supplement A), 264 -273, consisted of a mixture of eggs, wheat flour, commercial mashed potato, water and dye solution. According to Miles, Birmingham or Edinburgh Soils were formulated to mimic respiratory tract material. Other examples of artificial soils, which the FDA may consider as appropriate, include tissue culture media with 10% fetal bovine serum or red blood cells (10% or greater) in physiological saline.

If the devices used in the simulated-use test protocols are exposed to more than one type of organic material during actual clinical use, the artificial soil that represents the greatest challenge to the process should be selected.

The test organisms should be suspended in the artificial soil prior to inoculation onto the device in locations which represent the most difficult to sterilize. The effect of the artificial soil on the viability and recovery of the test organisms must be demonstrated. In addition, data from testing showing whether a dried inoculum or wet inoculum presents a more rigorous challenge to the sterilization process should be included in the submission. All other recommendations in the sterilizer guidance pertaining to the simulated-use testing should be followed.