5. Maintenance of Sterility After Removal From the Device

The instructions for use for most of the devices do not instruct the user on the proper procedure to remove instruments from the device, and on how to maintain sterility of the instruments or the processed portion of the instrument during the cool down period. There also exists the possibility that the heat transfer medium could serve as a source of contamination between patients. Because of the reported temperature gradients within the wells, there exists the possibility that heat resistant microorganisms could survive in the cooler regions near the top of the well and contaminate the instruments used upon the next patient as they are removed from the well. Furthermore, because endodontic dry heat sterilizers only process that portion of the instrument which has been inserted into the glass beads, there is the potential of contaminating a sterile field with a device which had not been properly processed.

6. Possibility of the Heat Transfer Medium Remaining Upon The Devices

Occasionally the heat transfer media has been observed to adhere to wet instruments. If the particles are not detected before the devices are inserted into the site, then they could cause blockage of the wound site or other adverse effects. This would cause significant problems if the heat transfer media were glass beads or molten metal (Ref. 1).

F. Benefit of the Devices

The endodontic dry heat sterilizer could be used to decontaminate endodontic instruments during a procedure on a single patient provided the instruments are properly cleaned to remove organic debris before insertion into the unit. In theory the number of microorganisms that would be introduced into the same site or into a new site on the same patient during a single procedure would be reduced. Once the procedure is over, the instruments should be processed using traditional methods of decontamination and sterilization before use in the next patient.

G. Need for Information for Risk/Benefit Assessment of the Device

The data in the literature indicate the lack of uniform sterilization parameters among the various glass bead sterilizers which have been marketed. Because of the temperature variation found within the wells of glass bead sterilizers, exposure of an instrument to an adequate sterilizing temperature is difficult to determine and must be confirmed independently for each instrument. Also determination of the sterilization exposure time is dependent upon instrument size and mass. As Koehler noted, some instruments never reach the appropriate temperature because of their size and mass (Ref. 6); and, as noted in the American Dental Association's ''Accepted Dental Therapeutics,'' 40th ed., endodontic dry heat sterilizers are not appropriate for large bulk instruments (Ref. 1).

Review of the claims being made for these devices suggests that manufacturers are expanding the claims beyond those originally defined in § 872.6730. The claims have been expanded to include the sterilization of general medical instruments and electrolysis and acupuncture needles, and to devices not regulated by FDA such as manicurist's instruments. The claims imply that these devices can be used as a substitute for the traditional methods of sterilization. Scarlett noted that endodontic dry heat sterilizers are not sterilizers, but are decontaminating devices and that they should not be used to sterilize instruments between patients (Ref. 8). No system exists for (1) Monitoring the exposure of the instrument to sterilization conditions, or (2) demonstrating that the sterilization exposure parameters have been achieved within the well. Only the portion of the instrument which is inserted into the heat transfer medium has the potential of being sterilized; the portion which is not inserted into the glass beads is not sterilized. The use of endodontic dry heat sterilizers with general medical instruments and with the implication as a substitute sterilization method raises serious safety and effectiveness questions which the manufacturers of these devices have not adequately addressed. There is the serious risk of infection through the use of inadequately processed instruments.

FDA believes that sufficient information may exist regarding the risks and benefits associated with the device, but the information must be assembled in such a way as to enable FDA to determine if the information provides reasonable assurance of the safety and effectiveness of the device for its intended use as defined in 21 CFR 860.7.

FDA classified the endodontic dry heat sterilizer into class III because it determined that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance. FDA has determined that the special controls that may now be applied to class II devices under the Safe Medical Devices Act of 1990 also would not provide such assurance. FDA has weighed the probable risks and benefits to the public health from the use of the device and believes that the literature reports and other information discussed above present evidence of significant risks associated with use of the device. These risks must be addressed by the manufacturers of endodontic dry heat sterilizers. FDA believes that the endodontic dry heat should undergo premarket approval to establish effectiveness and to determine whether the benefits to the patient are sufficient to outweigh any risk.

II. PMA Requirements

A PMA for this device must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified above, as well as a discussion of the effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence obtained from well-controlled studies, with detailed data, in order to provide reasonable assurance of the safety and effectiveness of the endodontic dry heat sterilizer for its intended use. The data must include the following information:

a. A general description of the sterilizer including its specifications, process parameters and process monitors;

b. An overview of the sterilization process with accompanying charts, graphs, or other visuals explaining all parameters;

c. A description of any test packs used in validating the performance of the endodontic dry heat sterilizer and in routine monitoring of the device;

d. Physical tests which demonstrate that the sterilizer achieves and maintains the physical process lethality conditions within specifications. The testing should describe how the process parameters and specifications were determined;

e. The microbiological performance tests must demonstrate that the device can sterilize to an acceptable sterilization assurance level all medical products identified in the labeling when used in accordance with the directions for use. The tests should be consistent with those used to validate sterilization processes including simulated and actual use tests;

f. Material compatibility tests must show that the medical devices identified in the labeling are compatible with the