heat transfer media used in these units have included glass beads, molten metal, metal beads, and salt. The instruments which are to be sterilized are inserted directly into the heat transfer medium. The units are defined in § 872.6730 as devices used to sterilize endodontic and other dental instruments by the application of dry heat which is supplied by the glass beads which have been heated by electricity.

The proposed rule to require premarket approval of the endodontic dry heat sterilizer applies to devices that were being commercially distributed before May 28, 1976, and to devices that were introduced into commercial distribution since that date which have been found to be substantially equivalent to predicate endodontic dry heat sterilizers.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring endodontic dry heat sterilizers to have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the device.

E. Risk Factors

The panel identified the primary risk to health as infection by stating that ''The inability of the device to sterilize adequately endodontic and other dental instruments may lead to transmission of microorganisms among patients and subsequent spread of infection.''

A review of the literature on endodontic dry heat sterilizers has identified the following problems associated with the use of these devices which contribute to the inability of endodontic dry heat sterilizers to sterilize instruments, including general medical instruments.

1. Temperature Variation Within the Well

There are many reports in the literature describing the temperature variation found within the wells of glass bead sterilizers (Refs. 2, 3, 4, 7, 10, and 11). Engelhardt et al. (Ref. 4) measured the temperature distribution in four brands of glass bead sterilizers at two different sites from the center and at six different depths in the well. He reported that the temperature within the well varied significantly depending upon location. The temperature was highest closest to the wall and midway down from the surface (Ref. 4). Corner also reported that near the periphery of the well the temperature varied by as much as 10 °C over time (Ref. 5). According to Ingle, glass bead sterilizers should not be used as a substitute for dry heat convection or steam sterilizers because of the temperature variations (Ref. 7).

2. Lack of Methods to Monitor the Recommended Exposure Times for Sterilization of the Instruments

The manufacturers' recommended exposure times for sterilization of instruments vary from as short as 2 seconds to 45 seconds for sterilizers whose purported operating temperatures are from 218 °C to 260 °C. However, location of the instruments in the well, the size and mass of the instruments, the number of instruments, and the shape of the instruments must be factored into the amount of time required for sterilization. Larger instruments composed of more metal take more time to heat than smaller instruments. Koehler reported that the time required to raise an instrument's temperature was dependent upon its size. Small instruments such as root canal files heated rapidly, while large instruments such as cotton pliers never reached the specified operating temperature (Ref. 6). Corner reported that instruments such as forceps, scalpels, spatulas, and scissors sterilized in rapid succession caused the temperature in the well to drop an average of 7 °C for each instrument and that it took 15 minutes for the temperature of the well to recover (Ref. 2). Smith reported sterilization times of 15 seconds to kill orthodontic bands contaminated with *Staphylococcus albus* and 45 seconds for bands contaminated with *Bacillus subtilis* spores; but if five bands were sterilized simultaneously, then the sterilization times doubled (Ref. 10). Fahid reported that a No. 60 file, which was the largest file tested in the study, was the most difficult to sterilize. The difficulty was attributed to two factors: the large mass of the file, and the air trapped in the deep trough since air is a poor heat conductor (Ref. 5). Engelhardt described sterilization times for endodontic instruments ranging from 15 to more than 100 seconds in glass bead sterilizers, and in some cases, the 100 seconds were not sufficient to achieve sterilization (Ref. 4). Schutt et al. found that it took 60 seconds to sterilize dental burs. He also emphasized that the temperature at the depth of the immersion of the burs should be measured and that the minimum temperature should be at least 175 °C at 2 millimeters (mm) below the surface and 240 °C at 15 mm below the surface (Ref. 9). It has been reported in the literature that glass bead sterilizers have been shown to be effective only with small instruments that can be imbedded into the heat transfer media and that their effectiveness has not been demonstrated for instruments of larger bulk. The insertion of large instruments would reduce the temperature of the glass beads below the minimum temperature required for sterilization (Ref. 1). Heat conduction in a large, partially imbedded device would be variable.

Precleaning of the instruments before insertion into the glass bead sterilizer is critical to the effectiveness of the device. Engelhardt demonstrated that if endodontic instruments were contaminated with a protein load (blood), the time required for sterilization was more than doubled. Such adverse conditions can easily be found in infected or gangrenous pulp. Spores, which are more resistant to sterilization processes than vegetative organisms, have been found in the oral cavity and cultured from pulp material (Ref. 4).

3. Lack of Methods to Monitor the Performance/Sterilization Efficacy of the Device

There are no identified methods for the routine monitoring of the sterilization efficacy of the endodontic dry heat sterilizer such as the ones which exist with the traditional sterilization methods, i.e., steam autoclaves, hot air dry heat sterilizers, or ethylene oxide sterilizers. Chemical and biological indicators are available for routine monitoring of the efficacy of the cycle parameters and for the validation of the process specifications for these traditional sterilizers. The data in the literature, as noted above, suggest that the user can not be assured that instruments inserted into an endodontic dry heat sterilizer will be reliably exposed to the minimum cycle parameters required for sterilization, i.e., exposure of the device to a set temperature for a specified time.

4. Variability of the Warm-up Times for Glass Bead Sterilizers

Reported warm-up times for these devices range from 15 minutes to 50 minutes with the average of 15–20 minutes. However, Corner reported that it took up to 30 minutes for the temperature of the glass beads to stabilize even though the manufacturer claimed that the device reached operating temperature within 10 minutes (Ref. 2).