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XII. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS. May 25, 1996. [Separate Pages] K962288

A. Submitter: Thomas Lansing, Pres. Pinnacle Products, Inc. St. Paul, MN 55107.

I. Classification Names and numbers:
Barrier, Cover, Protective, 80MMP

II. Common/Usual Name: Infection Control Barrier

III. Proprietary Names: Cover-All, Chair Sleeve, Drape-it-All, Tray Sleeve, related products.

IV. Establishment Registration Number: 2184071

V. Classification: This device has not been classified but is listed under code 80MMP in FDA 95-4246, "Classification Names for Medical Devices..." In the past, these devices were treated as accessories to the medical devices with which they were used, such as K-900093 which was cleared as an accessory to the dental handpiece, 76EFB, CFR 872.4200.

VI. Performance Standard: None established under section 514.

VII. Description of the Device: These disposable plastic shields are for use with various small hand-held dental instruments such as handpieces, ultrasonic scalers, jet polishers, contra angle handpieces, and similar hand instruments.
In other forms, they are used to cover various devices such as dental chairs, headpieces, accessory trays, x-ray heads, and others.
They are manufactured from clear polyethylene and formed to provide excellent tactile control combined with simple coverage and removal from the instrument.
These shields act as as physical barriers which augment existing infection control techniques and simplify existing clean-up and disinfection methods. They do not obviate, in any way, existing good dental practices such as sterilizing handpieces, hand instruments, etc between each patient.
The various products are designed to slip over the ends of the respective devices, allowing for attachment and/or protrusion of those parts of the devices that are inserted into the patient's mouth (instruments), or otherwise contact the patient (chair covers).
The products will be sold non-sterile, prepackaged, and are disposable, single use only.

VIII. Labels of the product and competitive devices are provided.

IX. Substantial Equivalence Statement. The "510(k) "Substantial Equivalence" Decision process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:
1. These products have the same intended use, to act as a physical barrier, augmenting existing infection control techniques and make clean-up and disinfection easier. These are

the same as those of the predicate devices. These products also have the same intended uses as similar products currently cleared for marketing by the 510(k) process.
2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market.
3. Predicate devices: This device is substantially equivalent to preamendment devices classified as shown above. Pinnacle Infection Control Products are substantially equivalent to many currently on the market, some of which have been cleared by the 510(k) process. Some recent examples cleared under the code MMP are: Hydro-Med Product's "Surgical Microscope Drape," K-944198 and Cottrell's "Protouch Overglove," K-952241. Earlier examples include Dentsply's "Disposa-Shield", K-900093.

End of Summary