K964113

NOV. 7, 1996

SUMMARY STATEMENT

M-PACT Corporation, registration number 1928508, wishes to file an intent to market sterile, single use nasal and sinus packings manufactured from formalized PVA sponge material. M-PACT will market the products under the trade names Clinicel and IVALON. The classification name for the device is epistaxis balloon (per 21 CFR section 874.4100).

Nasal and sinus packings are used to absorb excess body fluids after septal, turbinate, or rhinoplastic surgery or endoscopic sinus surgery, and for the control of epistaxis (i.e., nose bleeds). They are packaged individually as a sterile, dried and compressed sponge that is inserted into the nasal or sinus cavity. When expanded via absorption of blood after insertion, the nasal packing is intended to fill the necessary space to prevent lateral motion of the turbinate and provide gentle pressure on the mucosa. The sinus packing is intended to selectively pack only the ostiomeatal complex leaving the nasal cavity clear for breathing.

M-PACT nasal and sinus packings are made from formalized PVA sponge, which is a condensation product of polyvinyl alcohol and formaldehyde. Once the chemical reaction has taken place and the foam sponge has cured, the material is washed clean of any residual chemicals.

M-PACT's nasal and sinus products will be sold in different configurations with drawstrings and with and without airway tubes. The products will be provided sterile via gamma radiation in industry standard Tyvek/film and metalized polyester peelable pouches.

M-PACT Corporation is the manufacturer of the formalized PVA sponge material and will process it into different configurations of nasal and sinus products. M-PACT has contracted with Surgical Technologies Incorporated (facilities in Brea, CA and St. Paul, MN) to complete the packaging and sterilization processes. Surgical Technicologies Inc. contracts with Sterigenics for sterilization services. Sterilization and packaging protocols have been approved. The device is currently in the validation process and will not be marketed until the validation is complete.

Although this is a new product for M-PACT, it is a product which is substantially equivalent to nasal and sinus packs which are currently marketed in interstate commerce and which were on the market prior to the date of the enactment of the Medical Device Amendment of 1976 (May 28, 1976) (Ultracell Nasal Packing - K920358; Merocel Nasal Packing - pre-amendment, and the Expandacell Nasal Tapon — K900171, K912524). The M-PACT nasal and sinus packs are identical in size, shape, material composition and intended use as the Merocel Nasal Pack and Kennedy Sinus Pack currently marketed by Merocel Corporation, Mystic, CT (Xomed Jacksonville, FL), the Ultracell Nasal Pack currently marketed by Ultracell Medical Technologies, Stonington, CT, and the Expandacell™ Nasal Tampon marketed by Shippert Medical Technologies, Englewood, CO. Since the M-PACT nasal and sinus products are identical to product currently marketed by Merocel, Ultracell Medical Technologies, and Shippert Medical, the only changes will be in regard to labeling and packaging.