

MAY 14 1996

K 945105

510(k) Summary of Safety and Effectiveness

Submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

TreBay Medical Corporation

Poly/Platinum Pistons

1. Description

Poly/Platinum Pistons are implants for middle ear reconstruction. Available in a range of shaft diameters and lengths with loops for ossicular attachment. The device is a single patient use only implant, labeled as a restricted device for use only by a qualified health care professional and is individually sterile packaged, contained in a carton provided with an Important Product Information insert for the physician.

2. Identification of the Predicate Device

The Poly/Platinum Pistons are substantially equivalent in material, size, and design with the Plast-Pore pistons of Smith-Nephew Richards, Memphis, TN, differing in the ultra high molecular weight polyethylene material is solid, not porous as with the Plasti-Pore pistons, and are substantially equivalent to the fluoroplastic shaft Platinum pistons of Xomed, Inc., Jacksonville, FL.

3. Intended Use

The Poly/Platinum Pistons are intended for the elective reconstruction of the ossicular chain to facilitate conduction of sound energy from the ear drum to the inner ear. The prosthesis is implanted into the middle ear during a tympanoplasty procedure and is retained in the middle ear by the design configuration of the device.

4. Information Bearing on the Safety and Effectiveness

The Poly/Platinum Pistons have the same intended use and similar materials as the predicate devices. The use of solid UHMWPe (polyethylene) in the shaft of the piston is the difference in the material as the predicate devices use solid fluoroplastic or porous high density polyethylene. There are no additional characteristics known that should adversely affect the safety and effectiveness. The package insert provided with each device should be referred to for indications and patient information regarding the use of these implants.

Signature Dan H. Treace Date October 16, 1995
Dan H. Treace, Vice-President