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510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Osteogenics Co.
3234 64th Street
Lubbock, TX 79413
(806) 792-2311

Contact Person: Barry K. Bartee, DDS

Date of Preparation: January 29, 1997

II. DEVICE NAME

Proprietary Name: Cytoplast™ GBR

Common Name: Non-Absorbable Barrier Membrane

Classification Name: Implant, Endosseous For Bone Filling And/Or Augmentation.

III. PREDICATE DEVICES

Gore-Tex™ Regenerative Material (K922627; W.L Gore & Associates, Inc.)
TefGen-FD (K935137; American Custom Medical)
Imtec Biobarrier Membrane (K950306; Imtec Corporation)

IV. DEVICE DESCRIPTION

The Cytoplast™ GBR Non-Absorbable Barrier Membrane is composed of nanoporous high density polytetrafluoroethylene (n-PTFE) film with a nominal thickness of 250 microns and supplied in a variety of shapes and sizes. Membranes are supplied sterile in sealed pouches.

The biocompatibility of polytetrafluoroethylene (PTFE) has been established through a long history of use in a variety of long-term PTFE implant devices, such as PTFE vascular prostheses and cardiovascular patches. The Cytoplast™ GBR Non-Absorbable Barrier Membrane has been shown to be non-cytotoxic.

V. INTENDED USE

A temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.

VI. COMPARISON TO PREDICATE DEVICES

The Cytoplast™ GBR Non-Absorbable Barrier Membrane is identical in composition, function, and intended use to legally marketed predicate devices such as Gore-Tex™ Regenerative Material, TefGen-FD, and the Imtec Biobarrier Membrane.

Accordingly, Osteogenics Co. concluded that the Cytoplast™ GBR Non - Absorbable Barrier Membrane is safe and effective for its intended use and performs at least as well as the legally marketed predicate devices.