K970841

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510 (k) Summary of Safety and Effectiveness

SUBMITTED BY:

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F.D.A Registration Number: 1645158
Owner / Operator Number: 9003407

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CLASSIFICATION/COMMON OR USUAL NAME/ DEVICE NAME:

Classification Name: Precision expanded Titanium foil (CFR 878.3300)
Common/ Usual Name: Titanium Mesh.
Proprietary Name: IMTEC/ TitaniumMesh

PREDICATE DEVICE:

Leibinger, Micro-Titanium Augmentation Mesh (M-TAM™) K 862532
Osteomed, , Osteomed MSS (Ti Ridge Augmentation Material) K963394
Walter Lorenz Surgical, Inc., Ti Mini Bone Plate and Screws, K862482
TiMesh Inc., Reconstructive Surgery System,K923491

DEVICE DESCRIPTION:

The IMTEC/TitaniumMesh consists of a laser cut segment of precision expanded, flattened and annealed Titanium Mesh of a specific size dimension and pore dimension. The device will be marketed sterile.