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**510(k) Summary
Trebay Microdebrider**

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1.0 Date Prepared
August 16, 1996

2.0 Submitter (Contact)
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3.0 Device Name
Proprietary Name: Trebay Microdebrider
(The product's tradename has not been finalized and may be changed at a later date.)
Common Name(s): Electrical surgical shavers, electrical microdebriders, mastoid drills, microdrill, ENT drills, handpieces and cutting blades and burs.
Classification Name: ENT Surgical Drill

4.0 Device Classification
ENT Surgical Drill Procode 77 ERL Class II ; 21 CFR 874.4250 Tier 1
ENT Bur Procode 77 EQJ Class I ; 21 CFR 874.4140 Tier 1

5.0 Device Description
The TreBay Microdebrider system is comprised of the Power Control unit, foot pedal and three (3) types of motorized, reusable electric handpieces that use various interchangeable cutter blades and/or bur tips. The system can operate one, two or all three handpieces (one at a time) with suction and/or irrigation, depending on the handpiece. The Microdebrider System is intended for use by health care professionals and is labeled as a restricted device.

6.0 Intended Use
This device is intended for the cutting and removal of bone and tissues in ENT, otolaryngology / head and neck surgical procedures.

7.0 Substantial Equivalence
The modified Trebay Microdebrider / XPS System that is described in this notification has the same intended use as the originally cleared device, the same technological characteristics as other ENT surgical drills currently on the market, and does not raise any new issues of safety or effectiveness.