

K080070 K-HELIX PISTON AND PORP PARTIAL OSSICULAR REPLACEMENT PROSTHESESApr 17, 2008
98 days to decisionK080070 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k080070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Jan 10, 2008
Decision date	Apr 17, 2008
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Grace Medical, Inc.
Location	Memphis, TN, US
Contact	JEFF COBB
510(k) history	14 submissions · 14 cleared · 1994-2023

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