

K893134 APACERAM OSSICULAR PROSTHESISAug 3, 1989
100 days to decisionK893134 · Product code: **ETB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k893134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Apr 25, 1989
Decision date	Aug 3, 1989
Days to decision	100 days
Third-party review	No

APPLICANT

Company	Asahi Optical Co. C/O Rosati Associates, P.C.
Location	Japan, JP
Contact	SAMUEL C URSU
510(k) history	4 submissions · 4 cleared · 1986-1989

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