

K033554 SMART OFFSET STAPES PISTONNov 24, 2003
12 days to decisionK033554 · Product code: **ETB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k033554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Nov 12, 2003
Decision date	Nov 24, 2003
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary
Other names	SMART ISJ PROSTHESIS

APPLICANT

Company	Gyrus Ent LLC
Location	Bartlett, TN, US
Contact	GREGORY SREDIN
510(k) history	28 submissions · 28 cleared · 1997-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033554/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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