

**K130512 NITIFLEX STAPES PROSTHESIS, DETROIT PISTON,
SKARZYNSKI PISTON, ROBERSON STAPES PROSTHESIS**Dec 2, 2013
278 days to decisionK130512 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k130512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Feb 27, 2013
Decision date	Dec 2, 2013
Days to decision	278 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heinz Kurz GmbH Medizintechnik
Location	Amsterdam, Nh, NL
Contact	KRISTINA BITZER
510(k) history	14 submissions · 14 cleared · 1997-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130512/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 7, 2026