

K112616 NITIBOND STAPES PROSTHESIS, NITIPLAST STAPES PROSTHESISFeb 8, 2013
519 days to decisionK112616 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k112616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Sep 8, 2011
Decision date	Feb 8, 2013
Days to decision	519 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/k112616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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