

K033645 OTOFLEX 100 TYE 1012Mar 31, 2004
132 days to decisionK033645 · Product code: **ETY** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k033645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Auditory Impedance (ETY)
Date received	Nov 20, 2003
Decision date	Mar 31, 2004
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gn Otometrics A/S
Location	Taastrup, DK
Contact	PER PAPE THOMSEN
510(k) history	6 submissions · 6 cleared · 2004-2015

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