

K183201 Hearing Healthcare ProMar 6, 2019
107 days to decisionK183201 · Product code: **ETY** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k183201/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Auditory Impedance (ETY)
Date received	Nov 19, 2018
Decision date	Mar 6, 2019
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Db Diagnostic Systems, Inc.
Location	Weston, CT, US
Contact	Steven Levine
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	MEDlcept, Inc.
Contact	Scott Blood

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183201/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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