

K233658 Biowy Tym Tube (TT)Feb 16, 2024
93 days to decisionK233658 · Product code: **ETD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k233658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tympanostomy (ETD)
Date received	Nov 15, 2023
Decision date	Feb 16, 2024
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biowy Corporation
Location	Lake Forest, CA, US
Contact	Zhihua Lu
510(k) history	3 submissions · 3 cleared · 2018-2024

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