FDA 510(k) Premarket Notification

K233001 Bioscope Neuromonitor Device

CLEARED

Dec 13, 2024
448 days to decision

K233001 · Product code: **ETN** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k233001/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Sep 22, 2023
Decision date	Dec 13, 2024
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biosys Biyomedikal Muhendislik San. VE Tic. A.S.**
Location	Ankara, TR
Contact	Cemal Erdogan
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k233001/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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