

K243676 Duet External Drainage and Monitoring System (EDMS)

Mar 10, 2025
103 days to decision

K243676 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k243676/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Nov 27, 2024
Decision date	Mar 10, 2025
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Neurosurgery
Location	Goleta, CA, US
Contact	Foram Shukla
510(k) history	28 submissions · 27 cleared · 2001-2025

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Device record: <https://www.510kdatabase.net/k243676/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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