

K253580 Sterile Insulated Dilators, 5, 10, 16mm (MDT-0442S)Apr 26, 2026
160 days to decisionK253580 · Product code: **PDQ** · Neurology
Source: <https://www.510kdatabase.net/k253580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Nov 17, 2025
Decision date	Apr 26, 2026
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sterile, Insulated Dilator, 20mm (MDT-0469S)

APPLICANT

Company	Tedan Surgical Innovations
Location	Sugar Land, TX, US
Contact	Arya Monticino-Larsen
Website	http://www.tedansurgical.com
510(k) history	1 submissions · 1 cleared · 2026-2026

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