

K180542 NIM PAK NeedleAug 22, 2018
174 days to decisionK180542 · Product code: **PDQ** · Neurology
Source: <https://www.510kdatabase.net/k180542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Mar 1, 2018
Decision date	Aug 22, 2018
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NIM XPAK Needle; NIM Pedicle Probe

APPLICANT

Company	Boston Endo Surgical Tech,
Location	Bridgeport, CT, US
Contact	James Rogers
510(k) history	2 submissions · 2 cleared · 2018-2019

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