

K181578 DemeTECH PTFE Nonabsorbable Surgical SutureOct 11, 2018
118 days to decisionK181578 · Product code: **NBY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene (NBY)
Date received	Jun 15, 2018
Decision date	Oct 11, 2018
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Demetech Corporation
Location	Miami Lakes, FL, US
Contact	Linda Hernandez
510(k) history	5 submissions · 5 cleared · 2018-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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