

K180630 PTFE SURGICAL SUTUREApr 6, 2018
28 days to decisionK180630 · Product code: **NBY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k180630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene (NBY)
Date received	Mar 9, 2018
Decision date	Apr 6, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Omnia Spa
Location	Carmel, IN, US
Contact	Roberto Cerioli
510(k) history	3 submissions · 3 cleared · 2011-2018

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