

K161289 DURAFIBER AgAug 3, 2016
86 days to decisionK161289 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 9, 2016
Decision date	Aug 3, 2016
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Medical Limited
Location	Hull, GB
Contact	Samantha Neilson
510(k) history	20 submissions · 20 cleared · 2016-2024

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