

K192443 Dextile Anatomical MeshDec 6, 2019
91 days to decisionK192443 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 6, 2019
Decision date	Dec 6, 2019
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sofradim Production
Location	Ayer, MA, US
Contact	Benjamin Rochette
510(k) history	41 submissions · 41 cleared · 1999-2025

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