

K181094 Polydioxanone Surgical ScaffoldAug 2, 2018
99 days to decisionK181094 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 25, 2018
Decision date	Aug 2, 2018
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lntegra Lifesciences
Location	Princeton, NJ, US
Contact	Kendall L. Ciriaco
510(k) history	1 submissions · 1 cleared · 2018-2018

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