

K192452 LyograftSep 3, 2020
360 days to decisionK192452 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Sep 9, 2019
Decision date	Sep 3, 2020
Days to decision	360 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B. Bruan Surgical, SA
Location	Rubi, ES
Contact	Pau Turon Dols
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Qreg Consulting, LLC
Contact	Robin M Fatzinger

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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