FDA 510(k) Premarket Notification

K182087 DynaMesh-POSTERIOR

CLEARED

Oct 31, 2018
90 days to decision

K182087 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182087/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Aug 2, 2018
Decision date	Oct 31, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Feg Textiltechnik Forschungs- Und Entwicklungsgesellschaft**
Location	Aachen, DE
Contact	Stefan Schneemelcher
510(k) history	2 submissions · 2 cleared · 2016-2018

REGULATORY CONSULTANT

Consulting firm	**Meddiquest Regulatory Affairs, Ltd.**
Contact	Neil R. Armstrong

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