FDA 510(k) Premarket Notification

K132025 MESO BILAYER SURGICAL MESH

CLEARED

Oct 30, 2013
121 days to decision

K132025 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k132025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Jul 1, 2013
Decision date	Oct 30, 2013
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kensey Nash Corporation Dba Dsm Biomedical**
Location	Exton, PA, US
Contact	Susan Pileggi
510(k) history	7 submissions · 7 cleared · 2013-2018