FDA 510(k) Premarket Notification

CLEARED

K160869 Biodesign Tissue Graft, Biodesign Dural Graft, Biodesign Peyronie's Repair Graft

Apr 29, 2016
30 days to decision

K160869 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k160869/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Mar 30, 2016
Decision date	Apr 29, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Biotech Incorporated**
Location	West Lafayetta, IN, US
Contact	Perry W. Guinn
510(k) history	16 submissions · 16 cleared · 2013-2024