FDA 510(k) Premarket Notification

K162934 Biodesign Parastomal Hernia Repair Graft

CLEARED

Jul 10, 2017
263 days to decision

K162934 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162934/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Oct 20, 2016
Decision date	Jul 10, 2017
Days to decision	263 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