FDA 510(k) Premarket Notification

K142887 SIS Inguinal Hernia Repair Graft

CLEARED

Oct 1, 2015
364 days to decision

K142887 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k142887/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Oct 2, 2014
Decision date	Oct 1, 2015
Days to decision	364 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Biotech Incorprated**
Location	West Lafayette, IN, US
Contact	Perry W Guinn
510(k) history	4 submissions · 4 cleared · 2013-2015