FDA 510(k) Premarket Notification

K162388 CuraSeal Percutaneous Intraluminal Closure System for Anorectal Fistulas(PICS-AF)

CLEARED

Feb 3, 2017
162 days to decision

K162388 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Aug 25, 2016
Decision date	Feb 3, 2017
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Curaseal, Inc.**
Location	Santa Clara, CA, US
Contact	HAROLD F. CARRISON
510(k) history	1 submissions · 1 cleared · 2017-2017