FDA 510(k) Premarket Notification

K173734 RocaJJ Soft Stents

CLEARED

Mar 12, 2018
96 days to decision

K173734 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k173734/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Dec 6, 2017
Decision date	Mar 12, 2018
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Promepla Sam**
Location	Monaco, MC
Contact	Alexandre Bareille
510(k) history	5 submissions · 5 cleared · 2012-2018