FDA 510(k) Premarket Notification

K172666 CrossBow Fascial Closure System, CrossBow Fascial Closure System with Adaptor

CLEARED

Dec 1, 2017
87 days to decision

K172666 · Product code: **OCW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k172666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Sep 5, 2017
Decision date	Dec 1, 2017
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sutureease, Inc.**
Location	San Jose, CA, US
Contact	Scott Heneveld
510(k) history	1 submissions · 1 cleared · 2017-2017