FDA 510(k) Premarket Notification

CLEARED

K163615 Snowden-Pencer MicroLap 3mm Laparoscopic Instruments

May 4, 2017
133 days to decision

K163615 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k163615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 22, 2016
Decision date	May 4, 2017
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carefusion 2200, Inc.**
Location	Waukegan, IL, US
Contact	Jane Weber
510(k) history	12 submissions · 12 cleared · 2011-2021