FDA 510(k) Premarket Notification

K190075 Aurora Evacuator

CLEARED

Feb 12, 2019
27 days to decision

K190075 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k190075/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 16, 2019
Decision date	Feb 12, 2019
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rebound Therapeutics**
Location	Irvine, CA, US
Contact	Donald Atienza
510(k) history	6 submissions · 6 cleared · 2018-2021