FDA 510(k) Premarket Notification

K182380 AEON Endoscopic Stapler

CLEARED

Nov 28, 2018
89 days to decision

K182380 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Aug 31, 2018
Decision date	Nov 28, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lexington Medical, Inc.**
Location	Billerica, MA, US
Contact	Douglas MacBride
510(k) history	9 submissions · 9 cleared · 2017-2025