FDA 510(k) Premarket Notification

K191064 Argon Handset

CLEARED

Jun 12, 2019
51 days to decision

K191064 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 22, 2019
Decision date	Jun 12, 2019
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**New Deantronics Taiwan , Ltd.**
Location	Tu Cheng City, TW
Contact	Jane Liu
510(k) history	18 submissions · 18 cleared · 1998-2025