FDA 510(k) Premarket Notification

K180999 Mygen V-1000 RF System

CLEARED

Dec 11, 2018
239 days to decision

K180999 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 16, 2018
Decision date	Dec 11, 2018
Days to decision	239 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**RF Medical Co., Ltd.**
Location	Seoul, KR
Contact	Kwang S. Choi
510(k) history	4 submissions · 4 cleared · 2018-2023