FDA 510(k) Premarket Notification

K200639 LAP-iX

CLEARED

Sep 29, 2021
568 days to decision

K200639 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 10, 2020
Decision date	Sep 29, 2021
Days to decision	568 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sejong Medical Co., Ltd.**
Location	Paju-Si, KR
Contact	Yoojung Choi
510(k) history	7 submissions · 7 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov