FDA 510(k) Premarket Notification

K200559 CarpX

CLEARED

Apr 20, 2020
48 days to decision

K200559 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 3, 2020
Decision date	Apr 20, 2020
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pavmed, Inc.**
Location	New York, NY, US
Contact	Lishan Aklog
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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