FDA 510(k) Premarket Notification

K122383 EM3 AEM MONITOR AEM CONNECTORS

CLEARED

Jan 10, 2013
157 days to decision

K122383 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k122383/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 6, 2012
Decision date	Jan 10, 2013
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Encision, Inc.**
Location	Boulder, CO, US
Contact	JIM LEWIS
Website	http://encision.com/
510(k) history	10 submissions · 10 cleared · 2007-2020

Encision, Inc. designs and manufactures laparoscopic surgical instruments featuring Active Electrode Monitoring (AEM®) technology. The company, with a manufacturing facility in Boulder, US, specializes in burn protection systems and shielded surgical instruments for minimally invasive procedures. Encision has received FDA 510(k) clearances from total submissions since 2007. All cleared devices fall within the General & Plastic Surgery category. The company's last FDA 510(k) clearance was in 2020, and the company is currently inactive with no recent submissions. The compan...