

**K131949 AEM DISPOSABLE SUCTION IRRIGATION
ELECTRODES**Aug 26, 2013
60 days to decisionK131949 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k131949/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 27, 2013
Decision date	Aug 26, 2013
Days to decision	60 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...