

K072789 DISPOSABLE AEM FIXED TIP ELECTRODES AND HANDPIECESOct 19, 2007
18 days to decisionK072789 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k072789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 1, 2007
Decision date	Oct 19, 2007
Days to decision	18 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Encision, Inc.
Location	Boulder, CO, US
Contact	JUDITH V KING
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...