FDA 510(k) Premarket Notification

CLEARED

K140006 ENDOSHIELD BURN PROTECTION SYSTEM

Jun 16, 2014
165 days to decision

K140006 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k140006/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 2, 2014
Decision date	Jun 16, 2014
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Encision, Inc.**
Location	Boulder, CO, US
Contact	MIKE BIGGS
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...