

**K090979 DISPOSABLE HANDLE ASSEMBLES, MODELS
DH0100 AND DH0500 SERIES**May 28, 2009
51 days to decisionK090979 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k090979/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Apr 7, 2009
Decision date	May 28, 2009
Days to decision	51 days
Third-party review	No
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...