

**K122580 AEM DISPOSABLE SUCTION IRRIGATION HANDSET
MODEL ES1700**Nov 9, 2012
78 days to decisionK122580 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k122580/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Aug 23, 2012 |
| Decision date | Nov 9, 2012 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | AEM DISPOSABLE SUCTION IRRIGATION ELECTRODES MODEL ES077X SERIES |

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...