FDA 510(k) Premarket Notification

# K182605 HS AMICA devices family

**CLEARED**

Oct 28, 2019
402 days to decision

K182605 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182605/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Sep 21, 2018 |
| Decision date | Oct 28, 2019 |
| Days to decision | 402 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **H.S Hospital Service S.P.A** |
| Location | Boca Raton, FL, US |
| Contact | Laura Lenzi |
| 510(k) history | 6 submissions · 6 cleared · 2004-2024 |