

**K220138 Surtron 80 D, Surtron 160, Surtron 200, Surtron Flash
160 HF, Surtron 400 HP**

Oct 5, 2022
260 days to decision

K220138 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k220138/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Jan 18, 2022 |
| Decision date | Oct 5, 2022 |
| Days to decision | 260 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Led Spa |
| Location | Aprilia, IT |
| Contact | Amalia Lamberti |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k220138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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