

K190336 Soniquence Bipolar ElectrodesJun 20, 2019
126 days to decisionK190336 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190336/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Feb 14, 2019 |
| Decision date | Jun 20, 2019 |
| Days to decision | 126 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Soniquence, LLC |
| Location | Baldwin, NY, US |
| Contact | Suzanne Lucas |
| Website | https://soniquence.com |
| 510(k) history | 6 submissions · 6 cleared · 2019-2026 |

Soniquence, LLC develops radiofrequency surgical technology for medical, dental, and veterinary practices. The company operates with a manufacturing facility in Baldwin, US. Soniquence specializes in high-frequency surgical devices utilizing patented 4.0 MHz and 1.7 MHz radiofrequency technology for precision cutting and hemostasis. The company has received FDA 510(k) clearances from total submissions. All submissions focus on General & Plastic Surgery devices. First clearance: 2019. Latest clearance: 2026. The company remains active in FDA regulatory submissions. Sonique...
