

K183611 Soniquence RF Generator and Soniquence ElectrodesMay 22, 2019
147 days to decisionK183611 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 26, 2018
Decision date	May 22, 2019
Days to decision	147 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...

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