

K191878 DEX DeviceJan 29, 2021
564 days to decisionK191878 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 15, 2019
Decision date	Jan 29, 2021
Days to decision	564 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dex Surgical
Location	Verrieres Le Buisson, FR
Contact	Guillaume Noury
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191878/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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