

K192491 Coolief Radiofrequency Generator (CRG) SystemFeb 21, 2020
163 days to decisionK192491 · Product code: **GXD** · Neurology
Source: <https://www.510kdatabase.net/k192491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Lesion, Radiofrequency (GXD)
Date received	Sep 11, 2019
Decision date	Feb 21, 2020
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avanos Medical, Inc.
Location	Alpharetta, GA, US
Contact	Thomas Kozma
510(k) history	8 submissions · 8 cleared · 2019-2025

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