

K243677 iovera° SystemDec 26, 2024
29 days to decisionK243677 · Product code: **GXH** · Neurology
Source: <https://www.510kdatabase.net/k243677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Surgical, Cryogenic (GXH)
Date received	Nov 27, 2024
Decision date	Dec 26, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pacira Biosciences, Inc.
Location	San Diego, CA, US
Contact	Niloufa Insanally
510(k) history	2 submissions · 2 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243677/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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