

**K211334 Iovera System**Sep 10, 2021  
130 days to decisionK211334 · Product code: **GXH** · Neurology  
Source: <https://www.510kdatabase.net/k211334/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Surgical, Cryogenic (GXH)
Date received	May 3, 2021
Decision date	Sep 10, 2021
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pacira Pharmaceuticals, Inc.</b>
Location	Fremont, CA, US
Contact	Kent Jones
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211334/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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