

**K213584 Reprocessed NRG Transseptal Needle**Apr 4, 2023  
508 days to decisionK213584 · Product code: **QLZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k213584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Septostomy Catheter, Reprocessed (QLZ)
Date received	Nov 12, 2021
Decision date	Apr 4, 2023
Days to decision	508 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovative Health, LLC</b>
Location	Scottsdale, AZ, US
Contact	Rick Ferreira
510(k) history	48 submissions · 48 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213584/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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