

K200060 Reprocessed NRG Transseptal NeedleJul 30, 2020
199 days to decisionK200060 · Product code: **QLZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k200060/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Septostomy Catheter, Reprocessed (QLZ)
Date received	Jan 13, 2020
Decision date	Jul 30, 2020
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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