

K211662 Reprocessed IntellaMap Orion High Resolution Mapping Catheter

Nov 18, 2021
170 days to decision

K211662 · Product code: **NLG** · Cardiovascular
Source: <https://www.510kdatabase.net/k211662/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intracardiac Mapping, High-density, Reprocessed (NLG) |
| Date received | Jun 1, 2021 |
| Decision date | Nov 18, 2021 |
| Days to decision | 170 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 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k211662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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