

K201806 Reprocessed PentaRay Nav eco High-Density Mapping Catheter

Jun 23, 2021
357 days to decisionK201806 · Product code: **MTD** · Cardiovascular
Source: <https://www.510kdatabase.net/k201806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Jul 1, 2020
Decision date	Jun 23, 2021
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sterilmed Inc. (Johnson and Johnson)
Location	Plymouth, MN, US
Contact	Jan Flegeau
510(k) history	1 submissions · 1 cleared · 2021-2021

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