

**K190716 Streamline 6491 Unipolar Pediatric Temporary Pacing Lead, Streamline 6492 Unipolar Temporary Atrial Pacing Lead, Streamline 6494 Unipolar Temporary Myocardial Pacing Wire, Streamline 6495 Unipolar Temporary Myocardial Pacing Lead**Aug 8, 2019  
142 days to decisionK190716 · Product code: LDF · Cardiovascular  
Source: <https://www.510kdatabase.net/k190716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Mar 19, 2019
Decision date	Aug 8, 2019
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic</b>
Location	Minneapolis, MN, US
Contact	Joven Almazan
Website	<a href="http://www.medtronic.com/us-en/index.html">http://www.medtronic.com/us-en/index.html</a>
510(k) history	33 submissions · 33 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...

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