

# K200795 LINQ II Insertable Cardiac Monitor, LINQ Mobile Manager, Device Command Library, Instrument Command Library, LINQ Tool Kit

Jul 3, 2020  
99 days to decision

K200795 · Product code: **MXD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k200795/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (with Arrhythmia Detection) (MXD)
Date received	Mar 26, 2020
Decision date	Jul 3, 2020
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Medtronic, Inc.</b>
Location	Mounds View, MN, US
Contact	Eric Kalmes
Website	<a href="https://www.medtronic.com">https://www.medtronic.com</a>
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...