

K190623 Cardioblade Pen Surgical Ablation Device, Cardioblade XL Pen Surgical Ablation DeviceMay 30, 2019
80 days to decisionK190623 · Product code: **OCL** · Cardiovascular
Source: <https://www.510kdatabase.net/k190623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Device, For Cutting, Coagulation, And/or Ablation Of Tissue, Including Cardiac Tissue (OCL)
Date received	Mar 11, 2019
Decision date	May 30, 2019
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic
Location	Minneapolis, MN, US
Contact	Rahul Shah
Website	http://www.medtronic.com/us-en/index.html
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...