

**K210449 Infinity™ OCT System, PASS OCT® Spinal System**Mar 18, 2021  
30 days to decisionK210449 · Product code: **NKG** · Orthopedic  
Source: <https://www.510kdatabase.net/k210449/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Special                               |
| Device classification | Posterior Cervical Screw System (NKG) |
| Date received         | Feb 16, 2021                          |
| Decision date         | Mar 18, 2021                          |
| Days to decision      | 30 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        | Shweta Sharma   |
| Website        | <a href="http://www.medtronic.com/us-en/index.html">http://www.medtronic.com/us-en/index.html</a> |
| 510(k) history | 32 submissions · 32 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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Device record: <https://www.510kdatabase.net/k210449/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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