FDA 510(k) Premarket Notification

**CLEARED**

# K201449 SimuPlus Flexible Annuloplasty Ring, SimuPlus Flexible Annuloplasty Band, SimuForm Semi-Rigid Annuloplasty Ring

Jul 1, 2020
30 days to decision

K201449 · Product code: **KRH** · Cardiovascular
Source: https://www.510kdatabase.net/k201449/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Ring, Annuloplasty (KRH) |
| Date received | Jun 1, 2020 |
| Decision date | Jul 1, 2020 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medtronic, Inc.** |
| Location | Mounds View, MN, US |
| Contact | Lisa Corbin |
| Website | https://www.medtronic.com |
| 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,...