FDA 510(k) Premarket Notification

# K062654 DEPUY SIGMA CRUCIATE RETAINING POROCOAT FEMORAL COMPONENTS

**CLEARED**

Sep 29, 2006
22 days to decision

K062654 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k062654/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH) |
| Date received | Sep 7, 2006 |
| Decision date | Sep 29, 2006 |
| Days to decision | 22 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **DePuy Orthopaedics, Inc.** |
| Location | Warsaw, IN, US |
| Contact | NANCY FRIDDLE |
| 510(k) history | 206 submissions · 204 cleared · 1998-2023 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k062654/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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