FDA 510(k) Premarket Notification

# K893762 PLUS TOTAL KNEE SYSTEM, (PPD) TIBIAL COMPONENT

**CLEARED**

Sep 15, 1989
119 days to decision

K893762 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k893762/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent - SN |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | May 19, 1989 |
| Decision date | Sep 15, 1989 |
| Days to decision | 119 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Orthomet, Inc.** |
| Location | Plymouth, MN, US |
| Contact | DENNIS H CRANE |
| 510(k) history | 60 submissions · 41 cleared · 1986-1995 |