FDA 510(k) Premarket Notification

# K094013 HLS KNEETEC SYSTEM

**CLEARED**

May 5, 2011
492 days to decision

K094013 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k094013/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | Dec 29, 2009 |
| Decision date | May 5, 2011 |
| Days to decision | 492 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Tornier** |
| Location | Concord, CA, US |
| Contact | SEVERINE BONNETON |
| 510(k) history | 44 submissions · 44 cleared · 1995-2012 |