

**K862837 OMNIFIT TOTAL KNEE PROSTHESIS SYSTEM**Dec 22, 1986  
150 days to decisionK862837 · Product code: **HSX** · Orthopedic  
Source: <https://www.510kdatabase.net/k862837/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent - SN  |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX) |
| Date received         | Jul 25, 1986   |
| Decision date         | Dec 22, 1986   |
| Days to decision      | 150 days   |
| Third-party review    | No   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Osteonics Corp.</b>                    |
| Location       | Mchenry, IL, US                           |
| Contact        | DENNIS H CRANE                            |
| 510(k) history | 178 submissions · 136 cleared · 1980-2000 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k862837/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 21, 2026