

**K113733 SMALL AND LARGE FRAGMENTS OSTEOSYNTHESIS
SYSTEM NEOFIX**Mar 23, 2012
95 days to decisionK113733 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k113733/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Dec 19, 2011 |
| Decision date | Mar 23, 2012 |
| Days to decision | 95 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Neortho Produtos Ortopedicos S/A |
| Location | San Diego, CA, US |
| Contact | KEVIN A THOMAS |
| 510(k) history | 5 submissions · 5 cleared · 2010-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113733/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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