

**K031428 SYNTHES (USA) LARGE EXTERNAL FIXATION  
CLAMPS-MR SAFE**Aug 8, 2003  
94 days to decisionK031428 · Product code: LXT · Orthopedic  
Source: <https://www.510kdatabase.net/k031428/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Appliance, Fixation, Nail/blade/plate Combination, Multiple Component, Metal Composite (LXT) |
| Date received         | May 6, 2003  |
| Decision date         | Aug 8, 2003  |
| Days to decision      | 94 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Synthes (Usa)</b>                      |
| Location       | Mchenry, IL, US                           |
| Contact        | BONNIE J SMITH                            |
| 510(k) history | 411 submissions · 394 cleared · 1977-2015 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031428/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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