

K013294 MONARCH SPINAL SYSTEMSOct 9, 2001
7 days to decisionK013294 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k013294/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received | Oct 2, 2001 |
| Decision date | Oct 9, 2001 |
| Days to decision | 7 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Depuyacromed |
| Location | Raynham, MA, US |
| Contact | LISA GILMAN |
| 510(k) history | 48 submissions · 48 cleared · 1999-2004 |

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