

**K945674 MANDIBULAR BONE DISTRACTOR**Jun 2, 1995  
196 days to decisionK945674 · Product code: **MQN** · Dental  
Source: <https://www.510kdatabase.net/k945674/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | External Mandibular Fixator And/or Distractor (MQN) |
| Date received         | Nov 18, 1994  |
| Decision date         | Jun 2, 1995   |
| Days to decision      | 196 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Howmedica Corp.</b>                    |
| Location       | Mchenry, IL, US                           |
| Contact        | MARY C SPICER                             |
| 510(k) history | 373 submissions · 325 cleared · 1976-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945674/> 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 14, 2026