

**K955012 MIZUHO RADIOLUCENT HEAD FRAME**Sep 12, 1996  
316 days to decisionK955012 · Product code: **HBL** · Neurology  
Source: <https://www.510kdatabase.net/k955012/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Holder, Head, Neurosurgical (skull Clamp) (HBL) |
| Date received         | Nov 1, 1995                                     |
| Decision date         | Sep 12, 1996                                    |
| Days to decision      | 316 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mizuho America, Inc.</b>           |
| Location       | Union City, CA, US                    |
| Contact        | LISA SCHWEITZER                       |
| 510(k) history | 5 submissions · 5 cleared · 1996-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955012/> 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 27, 2026