

**K120220 ADAPTAIN SOLUBLE IMPLANT MATERIAL**Jun 6, 2012  
133 days to decisionK120220 · Product code: **KHJ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k120220/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                             |
| Submission type       | Traditional  |
| Device classification | Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ) |
| Date received         | Jan 25, 2012   |
| Decision date         | Jun 6, 2012  |
| Days to decision      | 133 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ceremed , Inc.</b>                   |
| Location       | Los Angeles, CA, US                     |
| Contact        | CHELSEA MITCHELL                        |
| 510(k) history | 20 submissions · 20 cleared · 2004-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120220/> 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 June 2, 2026