

**K052528 AOC BONE WAX OSTENE, OSTEOTENE AND CERETENE**Oct 11, 2005  
27 days to decisionK052528 · Product code: **MTJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k052528/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Wax, Bone (MTJ)                    |
| Date received         | Sep 14, 2005                       |
| Decision date         | Oct 11, 2005                       |
| Days to decision      | 27 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ceremed , Inc.</b>                   |
| Location       | Los Angeles, CA, US                     |
| Contact        | TADEUSZ WELLISZ                         |
| 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/k052528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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