

**K030492 TITANIUM OSSICULAR REPLACEMENT SYSTEM**Mar 3, 2003  
12 days to decisionK030492 · Product code: **ETA** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k030492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Ossicular Prosthesis, Total (ETA)
Date received	Feb 19, 2003
Decision date	Mar 3, 2003
Days to decision	12 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Invotec International, Inc.</b>
Location	Jacksonville, FL, US
Contact	JEFFREY L AULL
510(k) history	16 submissions · 16 cleared · 1990-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030492/> 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 21, 2026