

**K003603 BIO HERADOR SG, BIO HEADER GG, HERADOR S,  
BIO HERADOR N, HERABOND, HERALOY G, ALBABOND, BIO  
MAINGOLD SG, MAINGOLD SG, HE**Jan 10, 2001  
50 days to decisionK003603 · Product code: EJT · Dental  
Source: <https://www.510kdatabase.net/k003603/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Nov 21, 2000
Decision date	Jan 10, 2001
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Jelenko Co.</b>
Location	Armonk, NY, US
Contact	RAPHAEL JUDKINS
510(k) history	12 submissions · 12 cleared · 1988-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003603/>; 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 July 2, 2026