

**K912195 PA-396 GOLD BASED/PRECIOUS METAL ALLOYS
CLIN USE**Jul 30, 1991
74 days to decisionK912195 · Product code: **EJS** · Dental
Source: <https://www.510kdatabase.net/k912195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Other Noble Metal (EJS)
Date received	May 17, 1991
Decision date	Jul 30, 1991
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Jelenko Co.
Location	Armonk, NY, US
Contact	MARCY KRAMER
510(k) history	12 submissions · 12 cleared · 1988-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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