

K831095 ROYALE IIAug 31, 1983
149 days to decisionK831095 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k831095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Apr 4, 1983
Decision date	Aug 31, 1983
Days to decision	149 days
Third-party review	No

APPLICANT

Company	Factor, li, Inc.
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1983-2000

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Device record: <https://www.510kdatabase.net/k831095/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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