

**K130076 PROMOLUX, PROMOLUX HI, WEROPRESS, PREMECO
PCS**Aug 22, 2013
220 days to decisionK130076 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k130076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Jan 14, 2013
Decision date	Aug 22, 2013
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merz Dental GmbH
Location	Concord, MA, US
510(k) history	9 submissions · 9 cleared · 2003-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130076/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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