FDA 510(k) Premarket Notification

K113539 REVOIS PRO IMPLANT STSYEM

CLEARED

May 3, 2013
520 days to decision

K113539 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k113539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 30, 2011
Decision date	May 3, 2013
Days to decision	520 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Riemser Arzneimittel AG**
Location	Durham, NC, US
Contact	CHRISTOPH WAHL
Website	http://www.riemser.com/
510(k) history	3 submissions · 3 cleared · 2012-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k113539/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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