

K051614 PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM, PRIMACONNEX INTERNAL CONNECTION PROSTHETICSSep 9, 2005
84 days to decisionK051614 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k051614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 17, 2005
Decision date	Sep 9, 2005
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lifecore Biomedical, Inc.
Location	Washington, DC, US
Contact	RACHEL KENNEDY
Website	http://www.lifecore.com/
510(k) history	34 submissions · 34 cleared · 1991-2007

Lifecore Biomedical, Inc. is a sterile injectable contract development and manufacturing organization (CDMO) and sodium hyaluronate producer with a manufacturing facility in Washington, US. The company specializes in formulation development, aseptic fill-finish, analytical testing, and stability services for pharmaceutical and medical device manufacturers. Lifecore received FDA 510(k) clearances from total submissions, with clearances spanning 1991 to 2007. The company's regulatory focus was predominantly Dental devices, representing 97% of submissions. This includes dent...