FDA 510(k) Premarket Notification

K062876 PRIMACONNEX CERAMIC ABUTMENTS

CLEARED

Nov 1, 2006
36 days to decision

K062876 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k062876/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 26, 2006
Decision date	Nov 1, 2006
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifecore Biomedical, Inc.**
Location	Washington, DC, US
Contact	BRIAN SMEKAL
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...