FDA 510(k) Premarket Notification

K072241 PRIMACONNEX CAD/CAM ABUTMENT SYSTEM

CLEARED

Nov 9, 2007
88 days to decision

K072241 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k072241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 13, 2007
Decision date	Nov 9, 2007
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifecore Biomedical, Inc.**
Location	Washington, DC, US
Contact	JUDITH MEDLOCK-HAYES
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...

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