

**K053643 STAGE- 1 TEMPORARY/HEALING CAP, MODEL
42021-42026**Jan 23, 2006
24 days to decisionK053643 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k053643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Dec 30, 2005
Decision date	Jan 23, 2006
Days to decision	24 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...

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