

K041324 CALMATRIX CALCIUM SULFATE BONE GRAFT BINDERJul 19, 2004
62 days to decisionK041324 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k041324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	May 18, 2004
Decision date	Jul 19, 2004
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lifecore Biomedical, Inc.
Location	Washington, DC, US
Contact	KIM E AVES
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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