

K931468 RESTORE HEX CYLINDER ENDOSSEOUS SYSTEMJul 12, 1994
475 days to decisionK931468 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k931468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 24, 1993
Decision date	Jul 12, 1994
Days to decision	475 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Lifecore Biomedical, Inc.
Location	Washington, DC, US
Contact	LYNN CUPERUS
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...
