

K944069 RESTORE TPS LHEX CYLINDER ENDOSSEOUS IMPLANT SYSTEMFeb 28, 1995
194 days to decisionK944069 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k944069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 18, 1994
Decision date	Feb 28, 1995
Days to decision	194 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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