FDA 510(k) Premarket Notification

K994205 MODIFICATION OF REGULAR DIAMETER SINGLE STAGE (RDS) TPS DENTAL IMPLANT SYSTEM

CLEARED

Feb 29, 2000
90 days to decision

K994205 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k994205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 1, 1999
Decision date	Feb 29, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifecore Biomedical, Inc.**
Location	Washington, DC, US
Contact	CAROLYN ANDERSON
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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