FDA 510(k) Premarket Notification

K954512 RESTORE SELF TAPPING DENTAL IMPLANT SYSTEM

CLEARED

Feb 23, 1996
148 days to decision

K954512 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k954512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 28, 1995
Decision date	Feb 23, 1996
Days to decision	148 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...