

K032774 RENOVA INTERNAL HEX IMPLANT SYSTEMNov 26, 2003
79 days to decisionK032774 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k032774/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 8, 2003
Decision date	Nov 26, 2003
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lifecore Biomedical, Inc.
Location	Washington, DC, US
Contact	Diane Brinza
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...
