FDA 510(k) Premarket Notification

K051501 ZIRACE

CLEARED

Oct 19, 2005
135 days to decision

K051501 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k051501/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 6, 2005
Decision date	Oct 19, 2005
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acucera, Inc.**
Location	Seul, KR
Contact	KYUNG-BIN LEE
510(k) history	2 submissions · 2 cleared · 2005-2007