FDA 510(k) Premarket Notification

K032454 SILHOUETTE(TM) IC OR SILHOUETTE(TM) & LASER-LOK (TM)

CLEARED

Mar 4, 2004
206 days to decision

K032454 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k032454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 11, 2003
Decision date	Mar 4, 2004
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Lok Intl., Inc.**
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	3 submissions · 3 cleared · 2004-2006