FDA 510(k) Premarket Notification

K153136 Initial LiSi Press

CLEARED

Jun 30, 2016
244 days to decision

K153136 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k153136/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Oct 30, 2015
Decision date	Jun 30, 2016
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GC America, Inc.**
Location	Alsip, IL, US
Contact	MARK HEISS
510(k) history	125 submissions · 125 cleared · 1993-2025