FDA 510(k) Premarket Notification

K081694 DENJECTOR

CLEARED

Sep 12, 2008
87 days to decision

K081694 · Product code: **EJI** · Dental
Source: https://www.510kdatabase.net/k081694/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Cartridge (EJI)
Date received	Jun 17, 2008
Decision date	Sep 12, 2008
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dxm Co., Ltd.**
Location	Great Neck, NY, US
Contact	MARIA GRIFFIN
510(k) history	6 submissions · 6 cleared · 2004-2020