FDA 510(k) Premarket Notification

K080761 BONART'S ARTEOTOMY OMI AND OPI ULTRASONIC SURGERY SYSTEM & ACCESSORIES

CLEARED

Aug 25, 2008
160 days to decision

K080761 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k080761/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Mar 18, 2008
Decision date	Aug 25, 2008
Days to decision	160 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Bonart Co., Ltd.**
Location	Hsingchang, Taipei Hsien, TW
Contact	ERIC L ONG
510(k) history	14 submissions · 14 cleared · 2000-2017