FDA 510(k) Premarket Notification

K080220 PIEZO ULTRASONIC DEVICE, MODEL ULTRASONIC BONE SURGERY

CLEARED

Jul 28, 2008
181 days to decision

K080220 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k080220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Drill, Bone, Powered (DZI)
Date received	Jan 29, 2008
Decision date	Jul 28, 2008
Days to decision	181 days
Third-party review	No
Summary / Statement	Statement
Other names	ULTRASONIC DEBRIDMENT DEVICE

APPLICANT

Company	**Italia Medica S.R.L.**
Location	Ormond Beach, FL, US
Contact	BERTHOIN CLAUDE
510(k) history	1 submissions · 1 cleared · 2008-2008