FDA 510(k) Premarket Notification

CLEARED

K183138 Certain BellaTek Express and BellaTek Flex Abutments

Jul 2, 2019
231 days to decision

K183138 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k183138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Nov 13, 2018
Decision date	Jul 2, 2019
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet 3i**
Location	Palm Beach Gardens, FL, US
Contact	Krupal Patel
510(k) history	12 submissions · 12 cleared · 2007-2019