FDA 510(k) Premarket Notification

K081666 ATLANTIS, ATLANTIS GEMINI, ATLANTIS GEMINI+ ABUTMENTS FOR ASTRA OSSEOSPEED 3.0 IMPLANTS

CLEARED

Oct 7, 2008
116 days to decision

K081666 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k081666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 13, 2008
Decision date	Oct 7, 2008
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Astra Tech, Inc.**
Location	Waltham, MA, US
Contact	BETSY A BROWN
510(k) history	28 submissions · 28 cleared · 1994-2012