FDA 510(k) Premarket Notification

K072306 BIOXTRA MOISTURIZING GEL

CLEARED

Nov 15, 2007
90 days to decision

K072306 · Product code: **LFD** · Dental
Source: https://www.510kdatabase.net/k072306/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	Aug 17, 2007
Decision date	Nov 15, 2007
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-X Healthcare S.A.**
Location	Washington, DC, US
Contact	EMALEE MURPHY
510(k) history	1 submissions · 1 cleared · 2007-2007