

K200193 Kisses Plus Implant SystemAug 6, 2021
557 days to decisionK200193 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k200193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jan 27, 2020
Decision date	Aug 6, 2021
Days to decision	557 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Achimhai Medical Corporation
Location	Hwaseong-Si, KR
Contact	Ji Ho Jung
510(k) history	3 submissions · 3 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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