

**K181604 Sildent Fast Light Body, Sildent Fast Heavy Body,
Sildent Bite**Nov 28, 2018
162 days to decisionK181604 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k181604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 19, 2018
Decision date	Nov 28, 2018
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hrs Co., Ltd.
Location	Pyongtaek, KR
Contact	Seunghwan Go
510(k) history	2 submissions · 2 cleared · 2014-2018

REGULATORY CONSULTANT

Consulting firm	Onbix Corporation
Contact	Yang Ho Dong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181604/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026