

K151262 Hyflex Heavy, Hyflex Mono, Hyflex LightSep 21, 2015
131 days to decisionK151262 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k151262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	May 13, 2015
Decision date	Sep 21, 2015
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osstem Implant Co., Ltd.
Location	Busan, KR
Contact	Heekwon Son
Website	https://www.osstem.com
510(k) history	68 submissions · 68 cleared · 2006-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151262/> 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 4, 2026