

**K253501 Hydro Print Premium Fast Set - 454g (1lb) (052037)**

Oct 31, 2025  
1 days to decision

K253501 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k253501/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Oct 30, 2025
Decision date	Oct 31, 2025
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Hydro Print Premium Regular Set - 454g (1lb) (052327); Chroma Print Premium Fast Set - 454g (1lb) (052457); Chroma Print Premium Regular Set - 454g (1lb) (051460); Perfil Pro - 454g (1lb) (056213); Perfil Pro+ - 454g (1lb) (056121); Perfil Pro Chroma - 454g (1lb) (056122); Hydro Print Premium Fast Set - Multi Pack (056205); Hydro Print Premium Regular Set - Multi Pack (056208); Hydro Print Premium Fast Set - 9,07Kg (20lb) (056204);

**APPLICANT**

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Company	<b>Vigodent Indústria E Comercio Ltda</b>
Location	Rio De Janeiro, BR
Contact	Catia Mara da Eira Hoehn
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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