

K191154 Hair Boom 69Jul 29, 2019
89 days to decisionK191154 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	May 1, 2019
Decision date	Jul 29, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wontech
Location	Daejeon, KR
Contact	Gyuri (Erin) Park
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	Nst Consultants, Inc.
Contact	Raymond R. Blanche

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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