

K201552 ApolloVue S100 Image SystemSep 2, 2020
84 days to decisionK201552 · Product code: **NQQ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k201552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Jun 10, 2020
Decision date	Sep 2, 2020
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Apollo Medical Optics, Ltd.
Location	Taipei City, TW
Contact	Chi-Hua Wu
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Elite Biomedical Consulting, Inc.
Contact	Feng-Yu Lee

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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