

**K220574 HYBRID S70**Apr 22, 2022  
53 days to decisionK220574 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k220574/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Feb 28, 2022
Decision date	Apr 22, 2022
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Digimed Co., Ltd.</b>
Location	Seoul, KR
Contact	Youngbae Kwon
510(k) history	4 submissions · 4 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220574/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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