

**K260032 Morph**May 13, 2026  
127 days to decisionK260032 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k260032/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 6, 2026
Decision date	May 13, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BeauBrain Healthcare, Inc.</b>
Location	Seoul, KR
Contact	Hyojin Kim
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>LK Consulting Group USA, Inc.</b>
Contact	Priscilla Chung

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260032/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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