FDA 510(k) Premarket Notification

K232569 CAREMIBRAIN

CLEARED

Sep 21, 2023
28 days to decision

K232569 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k232569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Aug 24, 2023
Decision date	Sep 21, 2023
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**General Equipment For Medical Imaging, S.A.**
Location	Valencia, ES
Contact	Maria Climent
510(k) history	3 submissions · 3 cleared · 2009-2023

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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

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Device record: https://www.510kdatabase.net/k232569/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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