



## Acknowledgement Letter

01/19/2022

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Dear Mor Sharon:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or [OPEQSubmissionSupport@fda.hhs.gov](mailto:OPEQSubmissionSupport@fda.hhs.gov).

Submission Number: Q220114

Received: 01/19/2022

Applicant: MICA Artificial Intelligence

Device: DENISE Software

We will notify you when the review of this submission document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health