Intended Use:

Integrated into a clinical network to assist a radiologist with quantifying Hippocampus volume for Alzheimer's progression.

Indications for Use:

This AI system is intended to be integrated into a clinical network to assist a radiologist for quantifying Hippocampus volume Alzheimer's progression. It is intended to provide auto-computed information of hippocampal volumes from for T2 MRI scans of the full brain from new patients, as their studies are committed to the clinical imaging archive, but it does not directly generate any diagnosis or potential findings.

FDA Validation Plan:

Patient Population Description for FDA Validation Dataset:

The ideal training data for this algorithm are T2 MRI scans of Male and Female patients aged 52 to 73 years. Moreover, a rectangular portion of a brain scan is cut out from every image series for a dataset of relevant volumes and converted to the NIFTI format.

Ground Truth Acquisition Methodology:

The silver standard has been followed when collecting the ground truth data. The ground truth data for this AI algorithm was collected and annotated by the trained radiologists in the radiology department and it is annotated into 3 categories which are 0-irrevant, 1-anterior segment of the hippocampus, 2-posterior segment of the hippocampus.

Algorithm Performance Standard:

The AI algorithm must show that the statistics (DICE score) of the auto-computed hippocampus volume of a normative brain in the FDA Validation dataset must match 95% confidence interval as reported in this paper (https://www.sciencedirect.com/science/article/pii/S2213158219302542).

Limitations:

This AI algorithm will perform well when the input data is cut to a rectangular portion of a brain scan rom every image series for a volume in the NIFTI format. It might not perform well when preprocessing steps are not applied properly on the input volume data and on other imaging formats.