

FDA Submission

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June 14, 2020

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	Name of Device: PneumoniaXNet	

1 Algorithm Description

1.1 General Information

Intended Use Statement:

Indications for Use:

Device Limitations:

Clinical Impact of Performance:

1.2 Algorithm Design and Function

« Insert Algorithm Flowchart »

DICOM Checking Steps:

Preprocessing Steps:

CNN Architecture:

1.3 Algorithm Training

Parameters:

- Types of augmentation used during training
- Batch size
- Optimizer learning rate
- Layers of pre-existing architecture that were frozen
- Layers of pre-existing architecture that were fine-tuned
- Layers added to pre-existing architecture

« Insert algorithm training performance visualization »

« Insert P-R curve »

Final Threshold and Explanation:

1.4 Databases

(For the below, include visualizations as they are useful and relevant)

Description of Training Dataset:

Description of Validation Dataset:

1.5 Ground Truth

1.6 FDA Validation Plan

Patient Population Description for FDA Validation Dataset:

Ground Truth Acquisition Methodology:

Algorithm Performance Standard: