AI MEDICAL DEVICE TRANSPARENCY

KEITH J. DREYER, DO, PhD, FACR, FSIIM
Chief Science Officer, ACR Data Science Institute
Chief Data Science Officer, Mass General Brigham
Associate Professor, Harvard Medical School

Transparency of Artificial Intelligence
Machine Learning-enabled Medical Devices
FDA Virtual Public Workshop

October 14, 2021
AI PRODUCT INFORMATION MUST BE ACCESSIBLE AND UNDERSTANDABLE TO AI CONSUMERS
Detailed specifics of the clinical use case?

How generalizable is the model architecture?

Only way to know how it was tested and on whom?

How to track the use and compliance with IFU?

How to trigger alerts for problems?

How are demographic limitations enforced?

How to provide info to all patients impacted?

How to decide which product is best for pop?

More specifics on the methods & product class

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## Directory of FDA Cleared AI Products

### 2021

<table>
<thead>
<tr>
<th></th>
<th>CT</th>
<th>MR</th>
<th>XRAY</th>
<th>MAM</th>
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<td>15</td>
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**Total:** 124
FDA Cleared AI Algorithms

Our list of FDA cleared AI algorithms provides valuable details on each model, bringing all of the relevant information together for easy access. Convenient summaries for each algorithm include model manufacturer, FDA product code, body area, modality, predicate devices, product testing and evaluation related to product performance, and clinical validation. Our Define-AI use cases match many of the models and those are listed under Related Use Cases. For other details, clicking on the model will take you directly to the FDA summary.

Check back regularly to see which new algorithms are available and have been added to the list. Send information on AI algorithms that are not listed and report missing information to DS@acr.org.
**DIRECTORY OF FDA CLEARED PRODUCTS**

![Image of FDA website showing a directory of medical devices](https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-machine-learning-ai-ml-enabled-medical-devices)

<table>
<thead>
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</table>
Missed a critical pulmonary nodule

Erroneously detected a rib end as a pulmonary nodule

1 year old boy with immune deficiency

Courtesy Texas Children’s Hospital
Child with Tuberous Sclerosis
Multiple white matter lesions inapparent on DL AI sequence

Courtesy Cincinnati Children’s Hospital
Child with cortical dysplasia – findings obscured on DL FLAIR
Missed a critical pulmonary nodule

4 year old girl with Wilm’s tumor

Courtesy Texas Children’s Hospital
AI MEDICAL DEVICE TRANSPARENCY

100’s

AI MANUFACTURERS

MANUFACTURER

MANUFACTURER

MANUFACTURER

MANUFACTURER

FDA PREMARKET TESTING PARAMETERS

10,000’s

AI CONSUMERS

AI PURCHASERS

AI USERS

PATIENTS

FOOD & DRUG ADMINISTRATION

REQUIRE A SPECIFIC SET OF TESTING PARAMETERS TO BE INCLUDED IN PUBLIC FACING DOCUMENTS FOR ALL AI REGULATORY PATHWAYS

K. DREYER (10/2021)
AI MEDICAL DEVICE TRANSPARENCY

100's

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FDA PREMARKET TESTING PARAMETERS

K. DREYER (10/2021)
AI MEDICAL DEVICE TRANSPARENCY

I. POPULATION DEMOGRAPHICS

II. ACQUISITION DEVICES
   • Make, Model, Version, Protocols, Contrast

III. TECHNICAL MEASUREMENTS
    • Sens, Spec, PPV, NPV, AUROC

IV. FINDING METRICS
    • Conspicuity, Prevalence, Ground truth methods

V. ENHANCED PRODUCT IDENTIFICATION
   • Use Case Definition
   • CAD Classification vs Product Codes

K. DREYER (10/2021)
RECOMMENDATION

As you already impose rigorous tests on AI products, we ask that you require disclosure of critical testing parameters to the public, thereby dramatically reducing the need for every provider to retest every product to ensure their safe and effective use on all patients.

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