Transparent-AI Data Elements

Appendix				
Type	**Element Name**	**ID**	**Description**	**Required**
Model Identifier	Company name	MI.1	Name of company.	Yes
	Product name	MI.2	Name of FDA cleared product.	Yes
	Product version	MI.3	Version of the Algorithm used for inference.	Yes
	Product clearance date	MI.5	Date the product was cleared by FDA.	Yes
	Product FDA submission number	MI.6	Unique FDA ID that is referred as submission number.	Yes
	Additional information	MI.7	Free text field.	No
Model Type	Product category	MT.1	Indicate CAD type the product is cleared for.	Yes
	Additional information	MT.2	Free text field.	No
Model Characteristics	Data inclusion criteria	MC.1	Indicate the inclusion criteria for the product to run and provide output.	Yes
	Data exclusion criteria	MC.2	Indicate the exclusion criteria where the product will not run.	Yes
	Instructions for use	MC.3	Indicate if your company will be able to provide instructions for use document.	Yes
	Additional information	MC.4	Free text field.	No
Indications for Use	Clinical output	IU.1	What is the finding(s) that the product is intended to output	Yes
	Intended user	IU.2	Indicate the intended user of the product.	Yes
	Patient age	IU.3	Age group the product cleared is cleared for.	Yes
	Body area	IU.4	What target body part is the product intended for use.	Yes
	Modality	IU.5	Target modality for the product.	Yes
	Additional information	IU.6	Free text field.	No
Model Performance (performance testing and/or reader study)	Study type	MP.1	Indicate Reader Study or Stand-Alone Performance.	No
	Reference standard (ground truth)	MP.2	What was the reference standard (ground truth) based on?	No

	Number of readers	MP.3	If reader study was conducted, how many readers read each case?	No
	Number of cases	MP.4	How many image studies were used to evaluate model performance?	No
	Number of positive and negative cases	MP.5	Indicate number of positive and negative cases.	No
	Age range	MP.6	Indicate age range for data set.	No
	Sex ratio	MP.7	Indicate sex ratio of data set.	Yes
	Race/ethnicity ratio	MP.8	Indicate the race/ethnicity breakdown of data set.	Yes
	Geographic breakdown	MP.9	Indicate the geographic breakdown of data set.	Yes
	Manufacturer list	MP.10	Indicate the manufacturers in data set.	Yes
	Scanner list	MP.11	Indicate the scanners in data set.	Yes
	Number of sites	MP.12	How many sites were used.	No
	Percent of cases with and without finding	MP.13	Indicate the percent of positive and negative cases.	No
	Model accuracy	MP.14	Indicate the model accuracy.	No
	Model sensitivity	MP.15	Indicate the model sensitivity.	Yes
	Model specificity	MP.16	Indicate the model specificity.	Yes
	Additional information	MP.17	Free text field.	No
Details on Training Data Sets	Model dataset — Number of cases	TD.1	Indicate number of cases the model was trained on.	No
	Age range the model was trained on as well as age distribution	TD.2	Indicate age range the model was trained on as well as the age distribution.	No
	Sex ratio model was trained on	TD.3	Indicate sex ratio the model was trained on.	No
	Positive and negative cases	TD.4	Indicate number of positive and negative cases the model was trained on.	No
	Race/ethnicity ratio	TD.5	Indicate the race/ethnicity breakdown the model was trained on.	No
	Geographic breakdown	TD.6	Indicate the geographic breakdown the model was trained on.	No
	Manufacturers	TD.7	Indicate the manufacturers the model was trained on.	No
	Scanners	TD.8	Indicate the scanners that the model was trained on.	No
	Additional information	TD.9	Free text field.	No
Model Limitations, Warnings and Precautions	Supported scanners/ manufacturer	ML.1	Indicate if algorithm will only work on specific scanner or manufacturer.	No

	Slice thickness	ML.2	Indicate if there is a limit on slice thickness for product to perform.	No
	Supported hardware	ML.3	Indicate if product works only with specific hardware.	No
	Contrast agent	ML.3	Indicate if the product was cleared for contrast use.	No
	MRI field strength (BO)	ML.4	Indicate if the product was cleared for a specific magnetic field strength.	No
	Reconstruction kernel	ML.5	Describe the convolution kernel or algorithm used to reconstruct the data.	No
	Additional information	ML.6	Free text field.	No
Alternative Choices	Predicate and Reference devices		List out similar FDA-cleared products to your current product. This may include current predicate and reference devices listed in FDA summary.	No
Additional Information	Company point of contact		Describe how customers can reach out to company when needed	No