keywords: Artificial intelligence medical devices, regulatory approval, National Medical Products Administration

Supplementary Table 1: A mini-review on existing works for the approved AIMDs. AIMD=artificial intelligence medical device. FDA=US Food and Drug Administration. CE=Conformité Européenne.

Reference	Approved country	Time period	Total number	Analyzed characteristic
20201[1]	US (FDA)	Up until 2020 February	64	Approval year; Approval pathway; Medical specialty;
2021[2]	US (FDA)	Between January 2015 and December 2020	130	Body area; Risk; Multi-site/single site; Retrospective/prospective;
2021[3]	US (FDA); Europe (CE marked);	Between 2015 and 2020	222; 240;	Approval year; Approval pathway; Medical specialty; Company size (small/big); Company location;
2022[4]	US (FDA)	As of June 2021	343	Approval year; Approval pathway; Type of submission; Software only (Yes/No); Mobile application (Yes/No); Type of user; Medical specialty;

Supplementary Table 2: A description of previous works in terms of the data source, search strategy and selection criteria, key analysis result, and recommendations. AIMD=artificial intelligence medical device. FDA=US Food and Drug Administration. AI/ML=artificial intelligence and machine learning. CE=Conformité Européenne. AI=artificial intelligence. ML=machine learning. Regex=regular expression.

Reference	Data source	Search strategy and selection criteria	Key results	Recommendations
2020	FDA announcements & FDA.gov	Perform systematic web-based search for announcements of FDA approvals of AI/ML-based medical devices and algorithms and cross-check all approvals on FDA.gov	1. The vast majority was approved by the FDA with a 510(k) clearance; 2. The two main medical specialties with AI/ML-based medical innovations are Radiology and Cardiology;	1. There is a need from regulatory agencies to create their own databases. 2. Regulatory bodies could establish a clearer definition of what falls under the terms AI and ML.
2021	FDA documents of each approved device & one database maintained by American College of Radiology & one database created by Benjamens	Search all FDA documents for AI keywords to filter AIMDs and then merge with the other two existing databases	1. Most evaluations perform only retrospective studies; 2. The endpoints measured did not involve a side-by-side comparison of clinicians' performances with and without AI; 3. The number of evaluation sites and samples are often not publicly reported;	1. More prospective studies are needed to understand the impact of the AI decision tool on clinical practice. 2. The number of evaluation sites should be available to the public (such as clinicians, researchers, patients and so on) for them to make informed judgement about the reliability and bias. Multi-site evaluation is crucial to ensure algorithm performance.
2021	For the USA: FDA database for all medical devices; For Europe: Medical device database for every European country &	Apply keyword search, Regex search and manual review;	1. For the USA: The number of approved AIMDs increased over time. Most AIMDs were approved through the 510(k) pathway, and the majority was intended for professionals.	1. A publicly accessible database specific for AIMDs is important for Europe and more transparency is advisable rather than just summaries offering insufficient information for both FDA and

	other non-government sources such as Factiva, online websites and so on;		The top medical specialty according to the number of AIMDs is radiology, followed by cardiovascular devices. 2. For Europe: The number of AIMDs shows the similar growing trend. Most AIMDs were in radiology, followed by general hospital use and cardiovascular devices. 3. There is a large portion of AIMDs that were commonly approved by the FDA and CE marked. Among them, most were first approved in Europe before in the USA. 4. Only few devices (Three through the market approval pathway by the FDA and two class III devices by CE marked in the Europe) were qualified as high-risk;	Europe. 2. It needs to be reconsidered that whether more rigorous regulations for approval are needed.
2022	A list of AI/ML-enabled devices provided by FDA	The list is ready to use, thus do not need further processing;	1. the number of approvals increased in consecutive years. 2. radiology and cardiovascular are still two of the most leading medical specialties. 3. All devices were classified as class II by the FDA. 4. 152 out of 343 AIMDs did not have AI or any AI-related information mentioned in the FDA approval summaries. 5. The number of approved AIMDs largely reflects the increase in research output. 6. The indications for these devices reflect areas of clinical need.	1. A publicly accessible database specific for AIMDs is important for Europe and more transparency is advisable rather than just summaries offering insufficient information for both FDA and Europe. 2. It needs to be reconsidered that whether more rigorous regulations for approval are needed.

Supplementary Table 3: Characteristics of NMPA approved devices. NMPA=National Medical Products Administration. CT=Computed Tomography. FFR=Fractional Flow Reserve. ECG=Electrocardiogram. CTA=Computed Tomography Angiography. AI=artificial intelligence. X-ray=X-radiation.

NO.	Devices	Approval date	Medical specialty	Manufacture	Algorithm type	Body area	Origin city	Approved before
1	Computer-assisted diagnosis on diabetic retinopathy fundus	2020/8/7	ophthalmic	Shenzhen silicon intelligence	Deep learning	Eyes	Shenzhen	No
2	Computer-assisted diagnosis on diabetic retinopathy fundus	2020/8/7	ophthalmic	Shanghai airdoc	Deep learning	Eyes	Shanghai	No
3	Computer-assisted diagnosis on diabetic retinopathy fundus	2021/6/8	ophthalmic	Beijing Visionary Intelligence (Vistel)	Did not mention AI	Eyes	Beijing	No
4	Computer-assisted diagnosis on diabetic retinopathy fundus	2022/7/13	ophthalmic	Suzhou Volexcloud	Did not mention AI	Eyes	Suzhou	No
5	Computer-assisted diagnosis on diabetic retinopathy fundus	2022/8/16	ophthalmic	Beijing zhen health	Deep learning	Eyes	Beijing	No
6	Computer-assisted	2022/4/6	ophthalmic	Fujian	Did not	Eyes	Fujian	No

	diagnosis on diabetic retinopathy fundus			wedoctor	mention AI			
7	Computer-assisted diagnosis on Chronic glaucoma fundus	2022/8/31	ophthalmic	Tecent healthcare	Deep learning	Eyes	Shenzhen	No
8	Computer-assisted diagnosis of diabetic retinopathy and Chronic glaucoma on fundus	2022/8/16	ophthalmic	Beijing kangfuzi	Deep learning	Eyes	Beijing	No
9	Computer-assisted triage on lung nodule CT	2021/11/18	Radiology	Suzhou Volexcloud	Did not mention AI	Lung	Jiangsu	No
10	Computer-assisted triage on lung nodule CT	2023/4/23	Radiology	Ifly health	Deep learning	Lung	Anhui	No
11	Computer-assisted triage on lung nodule CT	2022/8/2	Radiology	Sensetime	Deep learning	Lung	Shanghai	No
12	Computer-assisted triage on lung nodule CT	2020/11/30	Radiology	Deep wise	Deep learning	Lung	Zhejiang	No
13	Computer-assisted triage on lung nodule CT	2022/5/26	Radiology	Yizhun	Deep learning	Lung	Guangxi	No
14	Computer-assisted triage on lung nodule CT	2022/4/29	Radiology	Shukun	Deep learning	Lung	Beijing	
15	Computer-assisted triage on lung nodule CT	2021/12/23	Radiology	YiTu	Deep learning	Lung	Zhejiang	
16	Computer-assisted triage on lung nodule CT	2022/4/29	Radiology	Huiyihuiyi ng	Deep learning	Lung	Beijing	
17	Computer-assisted detection on lung nodule CT	2020/12/11	Radiology	Infer vision	Deep learning	Lung	Beijing	Yes, 2020/7/02
18	Computer-assisted detection on lung nodule CT	2022/5/13	Radiology	Fosun Aitrox	Deep learning	Lung	Shanghai	
19	Computer-assisted detection on lung nodule CT	2021/6/23	Radiology	United imaging	Deep learning	Lung	Shanghai	
20	Computer-assisted triage on pneumonia CT	2021/8/6	Radiology	United imaging	Deep learning	Lung	Shanghai	
21	Computer-assisted triage on pneumonia CT	2021/3/26	Radiology	Deep wise	Deep learning	Lung	Zhejiang	
22	Computer-assisted triage on pneumonia CT	2021/3/26	Radiology	Infer vision	Deep learning	Lung	Beijing	
23	Computer-assisted triage on pneumonia CT	2021/11/12	Radiology	BioMind	Deep learning	Lung	Beijing	
24	Computer-assisted triage on pneumonia CT	2021/12/1	Radiology	Shukun	Deep learning	Lung	Beijing	
25	Computer-assisted triage on pneumonia CT	2021/8/16	Radiology	Tencent healthcare	Deep learning	Lung	Shenzhen	
26	Computer-assisted assessment on tuberculosis x-ray	2022/10/20	Radiology	Jiufeng healthcare	Deep learning	Lung	Jiangxi	
27	Computer-assisted assessment on thoracic	2022/8/16	Radiology	Siemens	Deep learning	Chest	Shanghai	

	CT							
28	Computer-assisted detection on Fracture CT	2020/11/9	Orthopedics	United imaging	Deep learning	Chest	Shanghai	
29	Computer-assisted triage on Chest fracture CT	2022/4/29	Orthopedics	Infer vision	Deep learning	Chest	Beijing	
30	Computer-assisted detection on rib fracture CT	2023/5/31	Orthopedics	Shukun	Deep learning	Chest	Beijing	
31	Computer-assisted detection on rib fracture CT	2023/4/28	Orthopedics	Deep wise	Deep learning	Multiple /others	Zhejiang	
32	Computer-assisted detection on fracture X-ray	2021/4/28	Orthopedics	Huiyihuiyi ng	Deep learning	Multiple /others	Beijing	
33	Computer-assisted assessment of Children Bone age estimation on hand X-ray	2021/3/18	Endocrinolo gy	Yitu	Deep learning	Hand	Zhejiang	
34	Computer-assisted assessment of Children Bone age estimation on hand X-ray	2022/3/2	Endocrinolo gy	Deep wise	Deep learning	Hand	Zhejiang	
35	Computer-assisted triage on intracranial hemorrhage CT	2023/4/10	Neurology	Shukun	Deep learning	Head	Zhejiang	
36	Computer-assisted triage on intracranial hemorrhage CT	2022/6/27	Neurology	Infervision	Deep learning	Head	Beijing	Yes, 2021/8/12
37	Computer-assisted triage on intracranial hemorrhage CT	2022/3/9	Neurology	United imaging	Deep learning	Head	Shanghai	
38	Computer-assisted triage on coronary artery stenosis CT	2020/11/3	Neurology	Shukun	Deep learning	Heart	Beijing	
39	Computer-assisted assessment on coronary artery stenosis CTA	2023/2/27	Cardiology	Deep wise	Deep learning	Heart	Zhejiang	
40	Computer-assisted assessment on coronary artery stenosis CTA	2023/2/22	Cardiology	Shukun	Deep learning	Heart	Beijing	
41	Computer-assisted assessment on cardiovascular CT	2022/8/16	Cardiology	Siemens	Deep learning	Heart	Shanghai	
42	Computer-assisted assessment on brain ischemia image	2022/8/4	Neurology	Neusoft	Did not mention AI	Head	Liaoning	
43	Computer-assisted assessment on ischemic stroke CT	2023/7/13	Neurology	Shukun	Deep learning	Head	Beijing	
44	Computer-assisted detection on Intestinal polyp endoscopy (EndoScreener)	2022/8/2	Internal medicine	Wision AI	Did not mention AI	Multiple /others	Sichuan	Yes, 2021/11/19
45	Computer-assisted detection on Intestinal polyp endoscopy	2023/5/12	Internal medicine	Wuhan ENDOANGEL Medical technology	Did not mention AI	Multiple /others	Hubei	
46	Computer-assisted detection on Intestinal polyp endoscopy	2023/6/1	Internal medicine	Tecent healthcare	Deep learning	Multiple /others	Shenzhen	
47	Computer-assisted	2023/1/5	Radiology	Deep wise	Deep	Breast	Zhejiang	

	detection on breast X-ray				learning			
48	Computer-assisted detection on breast X-ray	2023/7/13	Radiology	Biomind	Deep learning	Breast	Beijing	
49	Computer-assisted assessment on Head and Neck CT Angiography	2022/4/12	Radiology	Shukun	Deep learning	Head	Beijing	
50	Computer-assisted analysis on Cervical cell image	2023/3/8	Hematology	91360 medical technology	Deep learning	Multiple /others	Jiangsu	
51	Computer-assisted recognition of white blood cell images	2022/11/4	Hematology	Beijing xiaoying technology	Deep learning	Multiple /others	Beijing	
52	Intracranial Aneurysm Surgery Planning Software	2022/10/11	Neurology	Unistrong technology	artificial intelligence (region growing)	Multiple /others	Beijing	
53	Deep vessel FFR based on CTA	2020/1/14	Cardiology	Keya medical	Deep learning	Heart	Beijing	
54	FFR based on CTA	2023/2/3	Cardiology	Shukun	Deep learning	Heart	Beijing	
55	OmniECG C120 AI	2021/1/26	Cardiology	Lepu medical	Deep learning	Heart	Shenzhen	
56	AI-ECG platform	2020/1/22	Cardiology	Lepu medical	Deep learning	Heart	Shenzhen	Yes, 2018/11/19
57	OmniECG B120 AI	2020/7/22	Cardiology	Lepu medical	Deep learning	Heart	Shenzhen	
58	AI-ECG Tracker	2022/9/1	Cardiology	Lepu medical	Deep learning	Heart	Shenzhen	Yes, 2020/3/20
59	AccuContour	2022/8/2	Therapeutic radiology	Xiamen Manteia	Deep learning	Multiple /others	Xiamen	Yes, 202/2/28

Supplementary Table 4: Intended use for the approved AIMDs and their related medical specialty and classifications in body areas. AIMD=artificial intelligence medical device. CT=Computed Tomography. FFR=Fractional Flow Reserve. ECG=Electrocardiogram.

Medical specialty	**Body areas**	**Intend use subcategories**	**Number of approved AIMDs**
Ophthalmic	Eyes	Diabetic retinopathy & Chronic glaucoma diagnosis	8
Radiology	Lung	Lung nodule detection	11
	Lung	Tuberculosis assessment	1
	Lung	Pneumonia triage	6
	Chest	Thoracic CT scan assessment	1
	Breast	Breast lesion detection	2
	Head & neck	Head and neck artery stenosis	1
Orthopedics	Chest	Fracture detection	4
	Multiple/others		1
Endocrinology	hand	Bone age estimation	2
Neurology	Head	Intracranial hemorrhage triage	3
		Ischemic stroke	2
		Intracranial Aneurysm Surgery planning	1
Cardiology	Heart	Coronary artery stenosis assessment	3
		Cardiovascular CT assessment	1
		FFR computation	2
		ECG-based arrhythmia detection	4
Internal medicine	Multiple/others	Intestinal polyp endoscopy detection	3
Hematology	Multiple/others	Cell image analysis	2
Therapeutic radiology	Multiple/others	Countering	1

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