

# Research Assessment Task



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For your final assignment you need to describe the value chain of a Clinical AI technology of your choice and produce the following deliverables:

- a. **Proposal:** A brief description of the Clinical AI tool you have chosen, followed by a list of references describing its use, performance, utility and/or impact. (1-3 paragraphs and 3-10 references). This is due in Week 6.
- b. **Oral presentation:** A 5 minutes oral presentation using 1 slide (graphical executive summary) summarising your tool. This will take place in Week 10.
- c. **Final Report:** A report following a provided template detailing the use, performance, utility and/or impact of your chosen technology. It will include the graphical executive summary of your oral presentation (updated if needed) and a written section of between 1,000 and 2,000 words. This is due in Week 11.

# Choosing a Clinical AI tool

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- You can choose a tool you want to learn more about or you are already working with

OR

- You can find one you like searching amongst commercial products

# Software as a Medical Device

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Typically, AI diagnostic tools are approved using the **Software as a Medical Device** (SaMD)

Devices that make a definitive diagnosis are often class III (highest risk). The more impact the software has on the healthcare diagnosis/treatment decision, the higher the class attributed to it.

An FDA database listing approved AI/ML devices can be found here:

<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

**Content current as of:**  
10/05/2022

# FDA approvals (regulatory pathways)

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## Software as a medical device products

Level of FDA clearance	Description
510(k) clearance	A 510(k) clearance for an algorithm is granted when it has been shown to be at least as safe and effective as another similar, legally marketed algorithm. The submitter seeking this clearance must provide substantial proof of equivalence in their application. Without an approval of being substantially equivalent to the other algorithm, the one pending approval cannot be legally marketed.
Premarket approval	Premarket approval is issued to algorithms for Class III medical devices. The latter are those that can have a large impact on human health and as such, their evaluation undergo more thorough scientific and regulatory processes to determine their safety and effectiveness. In order to approve an application, the FDA determines that the device's safety and effectiveness is supported by satisfactory scientific evidence. Upon approval, the applicant can proceed with marketing the product.
De novo pathway	Regarding the de novo classification, it is used to classify those novel medical devices for which there are no legally marketed counterparts, but which offer adequate safety and effectiveness with general controls. The FDA performs a risk-based assessment of the device in question before approval and allowing the device to be marketed.

# FDA approvals De Novo

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm>

IDx-DR is a Class IIa Medical Device and the first ever FDA De Novo cleared autonomous AI.

## Device Classification Under Section 513(f)(2)(De Novo)

[FDA Home](#) [Medical Devices](#) [Databases](#)

The Food and Drug Administration Modernization Act (FDAMA) added the De Novo classification to the FD&C act, establishing an alternate pathway to classify new devices that have not been placed in class III after receiving a Not Substantially Equivalent (NSE) 510(k) submission. In this process, a sponsor who receives an NSE determination following notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the act.

The act was amended by section 607 of the Food and Drug Administration Modernization Act to provide a second option for De Novo Classification. In this second option, a sponsor may request FDA to make a risk-based classification of the device under section 513(a)(1) of the act without first submitting a 510(k).

[learn more...](#)

### Search Database

[Help](#) [Download Files](#)

Denovo Number	<input type="text"/>	<a href="#">Product Code</a>	<input type="text"/>
510(k) Number	<input type="text"/>	Priority Review	<input type="text"/>
Panel	<input type="text"/>	Device Name	<input type="text" value="IDx-DR"/>
Center	<input type="text"/>	Requester Name	<input type="text"/>
Decision Date	<input type="text"/>	to	<input type="text"/>
Sort By	<input type="text" value="Decision Date (descending)"/>		
<a href="#">Clear Form</a>		<input type="button" value="search"/>	



# FDA approvals (cont.)

---

1 result found

Device Name: *IDx-DR* Decision Date To:  
04/08/2022

results per page 10 ▾

[New Search](#)

[Download Files](#) | [More About De Novo](#)

Device Name	Requester	De Novo Number	510(k) Number	Decision Date
<a href="#">IDx-DR</a>	IDx, LLC	<a href="#">DEN180001</a>		04/11/2018

# FDA approvals – 510(k)

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

## 510(k) Premarket Notification

[FDA Home](#) [Medical Devices](#) [Databases](#)

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(l)(1)(A) FD&C Act) that is not subject to premarket approval.

[Learn more...](#)

### Search Database



Help



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510K Number

Type

[Product Code](#)

Center

Combination Products

☐

Applicant Name

Cleared/Approved In Vitro Products

☐

Device Name

Redacted FOIA 510(k)

☐

Panel

Third Party Reviewed

☐

Decision

Decision Date



to



Clinical Trials

☐

Sort by

[Quick Search](#)

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# Approvals in other countries

Muehlematter et al. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis. Lancet Digital Health 2021

Name	Region	Link
De novo premarket review database	US	https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
Premarket approval database	US	https://www.fda.gov/medical-devices/classify-your-medical-device/download-product-code-classification-files
FDA Product Code Classification	US	https://open.fda.gov/downloads/
openFDA Device 510(k) [/device/510(k)] database	US	https://www.dimdi.de/dynamic/de/medizinprodukte/datenbankrecherche/
Medizinprodukte-Anzeigen (DIMDI)	Europe (Germany)	http://aic.mhra.gov.uk/era/pdr.nsf/name?openpage&start=2001&count=1000
Public Access Database for Medical Device Registration (MHRA)	Europe (United Kingdom)	https://www.anism.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/DM-classes-IIa-IIb-III-et-DMIA-Communication-et-liste/(offset)/6
Liste des communications de dispositifs des classes IIa, IIb, et III (ANSM)	Europe (France)	http://www.salute.gov.it/interrogazioneDispositivi
Elenco dei dispositivi medici (Ministero della Salute)	Europe (Italy)	http://www.lifesciencesdirectory.at/
Austrian Life Sciences Directory (LISAVienna)	Europe (Austria)	https://www.vas.ehealth.fgov.be/registers/sadm/web/distribution/search
Medical Device Notifications (FAMHP)	Europe (Belgium)	

# FDA approvals (cont.)

[New Search](#)

[Back To Search Results](#)

<b>Device Classification Name</b>	<a href="#">diabetic retinopathy detection device</a>
<b>510(k) Number</b>	K213037
<b>Device Name</b>	IDx-DR v2.3
<b>Applicant</b>	Digital Diagnostics Inc. 2300 Oakdale Blvd Coralville, IA 52241
<b>Applicant Contact</b>	Ashley Miller
<b>Correspondent</b>	Hogan Lovells US LLP 1735 Market St., Floor 23 Philadelphia, PA 19103
<b>Correspondent Contact</b>	Kelliann Payne
<b>Regulation Number</b>	<a href="#">886.1100</a>
<b>Classification Product Code</b>	<a href="#">PIB</a>
<b>Date Received</b>	09/21/2021
<b>Decision Date</b>	06/17/2022
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	Ophthalmic
<b>510k Review Panel</b>	Ophthalmic
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Traditional
<b>Reviewed by Third Party</b>	No
<b>Combination Product</b>	No

# MHRA approvals

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<https://pard.mhra.gov.uk/>



Medicines & Healthcare products  
Regulatory Agency

**BETA**

This is a new service – your [feedback](#) will help us to improve it.

## Public Access Registration Database (PARD)

Enter Medical Device Type or Manufacturer Name: ?

SEARCH

[ADVANCED SEARCH](#)

The MHRA public access registration database (PARD) website allows you to find:

- Registered manufacturers
- Registered medical device types

# MHRA approvals (cont.)

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Type

**DEVICES**

MANUFACTURERS

Sort

ALPHABETICALLY

**DATE REGISTERED**

[Download CSV](#)

MHRA Reference Number: 25174

Date Registered: 01/07/2022

**SKINVISION B.V.**

**Manufacturer Address:**

Kraanspoor 28  
Amsterdam  
Netherlands  
1033 SE

**UK Responsible Person/Northern Ireland Authorised Representative:**

International Associates Limited

**Relationship:**

UK Responsible Person

**Representative Address:**

38 Queen Street  
Glasgow  
Scotland, United Kingdom  
G1 3DX

# FAMHP approvals

<https://www.vas.ehealth.fgov.be/registers/sadm/web/distribution/search>

Search criteria

Actors

Company:

Company FAMHP number:

Manufacturer:

Authorised representative:

Notifications of devices

FAMHP identification code:

Device name:

Device type: ☒ All  
☐ Implant / long term invasive  
☐ Mobile health application  
☐ Other

Risk class:

Reference:

Only products: ☐ with a date of deletion

Clear

Search

Notifications of devices

NIHDI notification code ↕	Device name ↕	Reference ↕	Manufacturer ↕	Distributor	Status ↕	First publication date ↕	Actions
<input checked="" type="checkbox"/>	SkinVision		Skin Vision B.V.	Skin Vision...	Published	19-06-2019	

1 result(s)

Export selection

Export All

Federal Agency for Medicines and Health Products (Agence fédérale des médicaments et des produits de santé)

# FAMHP approvals (cont.)

## Medical device

NIHDI notification code:	
Company FAMHP number:	71933
Enterprise number (CBE):	0723713634
Company:	Skin Vision B.V.
Manufacturer:	Skin Vision B.V.
Manufacturer country:	NL
Authorised representative:	
Authorised representative country:	
Type:	Mobile health application
Device name:	SkinVision
Reference:	
Risk class:	Class MDD I
URL:	<a href="http://www.skinvision.com">www.skinvision.com</a>
FAMHP notification code:	505200
NIHDI classification code:	FAMHP
Date of introduction on the market:	17-06-2019
Indicated price (€):	30
First publication date:	19-06-2019

# TGA approvals

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<https://www.tga.gov.au/>

Search the TGA website.

 [Listen](#)  [Print](#)  [Share](#)

## Type

☐ ARTG (1)

SkinVision



**1** result(s) found, displaying 1 to 1

16 June 2018 | ARTG

**[Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Medical image management system application software \(304431\)](#)**

Australian Register of Therapeutic Goods (ARTG) information for Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Medical image management system application software.



# TGA approvals

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## ARTG ID 304431

ARTG Name	Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Medical image management system application software
Product name	Medical image management system application software
ARTG Date	16 June 2018
Registration Type	Device
Therapeutic good type	MD
Sponsor	<a href="#">Emergo Asia Pacific Pty Ltd T/a Emergo Australia</a>
Manufacturers	SkinVision BV
Licence category	INC
Licence status	A
Licence class	Class 1
Summary	<a href="#">Download PDF</a>

# Scientific papers

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<https://pubmed.ncbi.nlm.nih.gov/advanced/>

## PubMed Advanced Search Builder



[User Guide](#)

Add terms to the query box

Title/Abstract



IDx-DR



ADD ▾

[Show Index](#)

Query box

Enter / edit your search query here

Search ▾

# Scientific papers (cont.)

[Search](#)[Advanced](#) [Create alert](#) [Create RSS](#)[User Guide](#)[Save](#)[Email](#)[Send to](#)

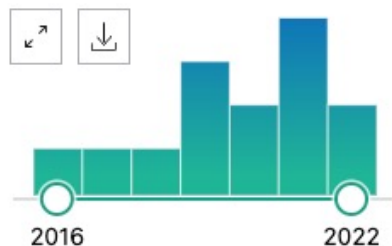
Sorted by: Best match

[Display options](#) [MY NCBI FILTERS](#)

12 results

[<<](#) [<](#) Page 1 of 2 [>](#) [>>](#)

RESULTS BY YEAR



TEXT AVAILABILITY

- ☐ Abstract
- ☐ Free full text
- ☐ Full text

ARTICLE ATTRIBUTES

☐ **IDx-DR for Diabetic Retinopathy Screening.**

1 Savoy M.

Cite *Am Fam Physician.* 2020 Mar 1;101(5):307-308.PMID: 32109029 **Free article.** No abstract available.

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☐ **Analysis and Comparison of Two Artificial Intelligence Diabetic Retinopathy Screening Algorithms in a Pilot Study: IDx-DR and Retinalyze.**

2 Grzybowski A, Brona P.

Cite *J Clin Med.* 2021 May 27;10(11):2352. doi: 10.3390/jcm10112352.PMID: 34071990 **Free PMC article.**

Share

As different screening solutions are now available commercially, with more in the pipeline, choosing a system is not a simple matter. Based on the images gathered in a local **DR** screening program we performed a retrospective comparison of **IDx-DR** and Retinalyze ...

# Clinical trials registry

<https://www.clinicaltrials.gov/ct2/search/advanced?cond=&term=&cntry=&state=&city=&dist=>

Note: it includes  
observational  
studies

**Search** [Help](#)

**Condition or disease:**

X

**Other terms:**

X

**Study type:**

All Studies

▼ X

**Study Results:**

All Studies

▼ X

**Status:**

**Recruitment:**

☐ Not yet recruiting

☐ Recruiting

☐ Enrolling by invitation

☐ Active, not recruiting

☐ Suspended

☐ Terminated

☐ Completed

☐ Withdrawn

☐ Unknown status

**Expanded Access:**

☐ Available

☐ No longer available

☐ Temporarily not available

☐ Approved for marketing

**Age:**

X

years

OR

**Age Group:**

☐ Child (birth-17)

☐ Adult (18-64)

☐ Older Adult (65+)

**Sex:**

All

▼ X

**Accepts Healthy Volunteers:**

☐ Healthy volunteers may participate in the study

**Intervention/treatment:**

IDx-DR

X

**Title / Acronym:**

X

**Outcome Measure:**

X

**Sponsor / Collaborator:**

X

**Sponsor (Lead):**

X

**Study IDs:**

X

# Clinical trials registry (cont.)

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	<a href="#">ACCESS 2: AI for pediatric diabetic Eye examS Study 2</a>	<ul style="list-style-type: none"> <li>Type 1 Diabetes</li> <li>Type 2 Diabetes</li> <li>Cystic Fibrosis-related Diabetes</li> </ul>	<ul style="list-style-type: none"> <li>Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam</li> </ul>	<ul style="list-style-type: none"> <li>Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States</li> </ul>
2	<input type="checkbox"/>	Completed	<a href="#">ACCESS: AI for pediatric diabetic Eye examS Study</a>	<ul style="list-style-type: none"> <li>Type 1 Diabetes</li> <li>Type 2 Diabetes</li> </ul>	<ul style="list-style-type: none"> <li>Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam</li> </ul>	<ul style="list-style-type: none"> <li>Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States</li> </ul>
3	<input type="checkbox"/>	Completed	<a href="#">Computer Detection of Diabetic Retinopathy Compared to Clinical Examination</a>	<ul style="list-style-type: none"> <li>Diabetic Retinopathy</li> </ul>	<ul style="list-style-type: none"> <li>Procedure: Photography of the retina</li> <li>Procedure: Retinal photography</li> </ul>	<ul style="list-style-type: none"> <li>Barnet Dulaney Perkins Eye Center Mesa, Arizona, United States</li> <li>Barnet Dulaney Perkins Eye Center Phoenix, Arizona, United States</li> <li>Iowa Eye Center Cedar Rapids, Iowa, United States</li> <li>(and 4 more...)</li> </ul>

# Clinical trials registry (cont.)

## Find a study (all fields optional)


### Status

- ☐ Recruiting and not yet recruiting studies
- ☐ All studies

### Condition or disease (For example: breast cancer)



### Other terms (For example: NCT number, drug name, investigator name)



### Country



**Search**

[Advanced Search](#)

# Clinical trials registry (cont.)

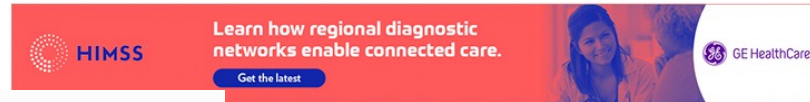
Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Completed	<a href="#">A Multi-center Study to Evaluate Performance of an Automated Device for the Detection of Diabetic Retinopathy</a>	<ul style="list-style-type: none"> <li>Diabetic Retinopathy</li> </ul>		
2	<input type="checkbox"/>	Recruiting	<a href="#">ACCESS 2: AI for pediatric diabetic Eye examS Study 2</a>	<ul style="list-style-type: none"> <li>Type 1 Diabetes</li> <li>Type 2 Diabetes</li> <li>Cystic Fibrosis-related Diabetes</li> </ul>	<ul style="list-style-type: none"> <li>Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam</li> </ul>	<ul style="list-style-type: none"> <li>Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States</li> </ul>
3	<input type="checkbox"/>	Completed	<a href="#">ACCESS: AI for pediatric diabetic Eye examS Study</a>	<ul style="list-style-type: none"> <li>Type 1 Diabetes</li> <li>Type 2 Diabetes</li> </ul>	<ul style="list-style-type: none"> <li>Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam</li> </ul>	<ul style="list-style-type: none"> <li>Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States</li> </ul>
4	<input type="checkbox"/>	Completed	<a href="#">Computer Detection of Diabetic Retinopathy Compared to Clinical Examination</a>	<ul style="list-style-type: none"> <li>Diabetic Retinopathy</li> </ul>	<ul style="list-style-type: none"> <li>Procedure: Photography of the retina</li> <li>Procedure: Retinal photography</li> </ul>	<ul style="list-style-type: none"> <li>Barnet Dulaney Perkins Eye Center Mesa, Arizona, United States</li> <li>Barnet Dulaney Perkins Eye Center Phoenix, Arizona, United States</li> <li>Iowa Eye Center Cedar Rapids, Iowa, United States</li> <li>(and 4 more...)</li> </ul>



# Clinical trials registry (cont.)

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	<a href="#">ARTificial Intelligence-based Smartphone Application for Skin Cancer Detection</a>	<ul style="list-style-type: none"><li>• Skin Cancer</li></ul>		<ul style="list-style-type: none"><li>• Department of Dermatology, Ghent University Hospital Ghent, East Flanders, Belgium</li></ul>
2	<input type="checkbox"/>	Recruiting	<a href="#">Melanoma Detection in Switzerland With VECTRA</a>	<ul style="list-style-type: none"><li>• Melanoma (Skin)</li></ul>	<ul style="list-style-type: none"><li>• Device: 3D imaging Total Body Photography Vectra® WB360</li><li>• Device: 2D imaging FotoFinder ATBM® Master imaging system</li><li>• Device: Smartphone application (<b>SkinVision®</b>)</li><li>• Other: Standard-of-care clinical assessment of the skin</li></ul>	<ul style="list-style-type: none"><li>• Department of Dermatology, University Hospital Basel Basel, Switzerland</li></ul>

# Other sources



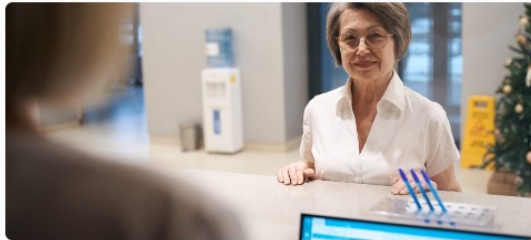
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### Latest



### Trending



9 June 2023  
Hills calls in administrators after Western Sydney patient infotainment system lawsuit loss



30 May 2023  
Orion Health's three-pillar strategy for unified healthcare through a digital front door



30 May 2023

### Health pilots generative AI chatbot

11:10 am | June 26, 2023

ending time searching through training  
Health team members can quickly access  
at streamline their administrative burdens  
OpenAI services on Microsoft Azure.



Can regional diagnostic networks address data silos and promote



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## AI in Healthcare

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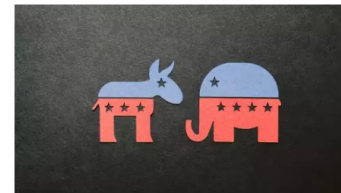
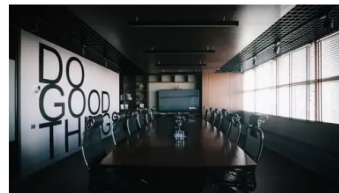
JUN 20, 2023 · 9 MIN READ

### AI in health care, ending physician b MPH [Podcast]

The AMA Update covers a range of health care topics a  
the new president's priorities for the next year.

/ SERIES /

LEADERSHIP AMA Update Podcast



### Around the web

CARDIOVASCULAR BUSINESS

AI correctly IDs ventricular arrhythmias in 88%  
of patients with sustained VT

New research suggests AI could offer  
physicians a new, state-of-the-art approach to  
sudden cardiac arrest risk management.



UNSW SYDNEY



CENTRE FOR  
BIG DATA RESEARCH  
IN HEALTH



# Not as SaMD

PKS rebrands as Beamtree, buys AI start-up Ainsoff and data analytics firm Potential(x)

CLINICAL PAPER | VOLUME 188, 109821, JULY 2023

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[Levi Bassin](#)   • [Jacques Raubenheimer](#) • [David Bell](#)

Open Access • Published: May 05, 2023 • DOI: <https://doi.org/10.1016/j.resuscitation.2023.109821> •

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+4 authors

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AI?



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