Research Assessment Task

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CENTRE FOR BIG DATA RESEARCH IN HEALTH

Research Assessment Task

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

- 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

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)

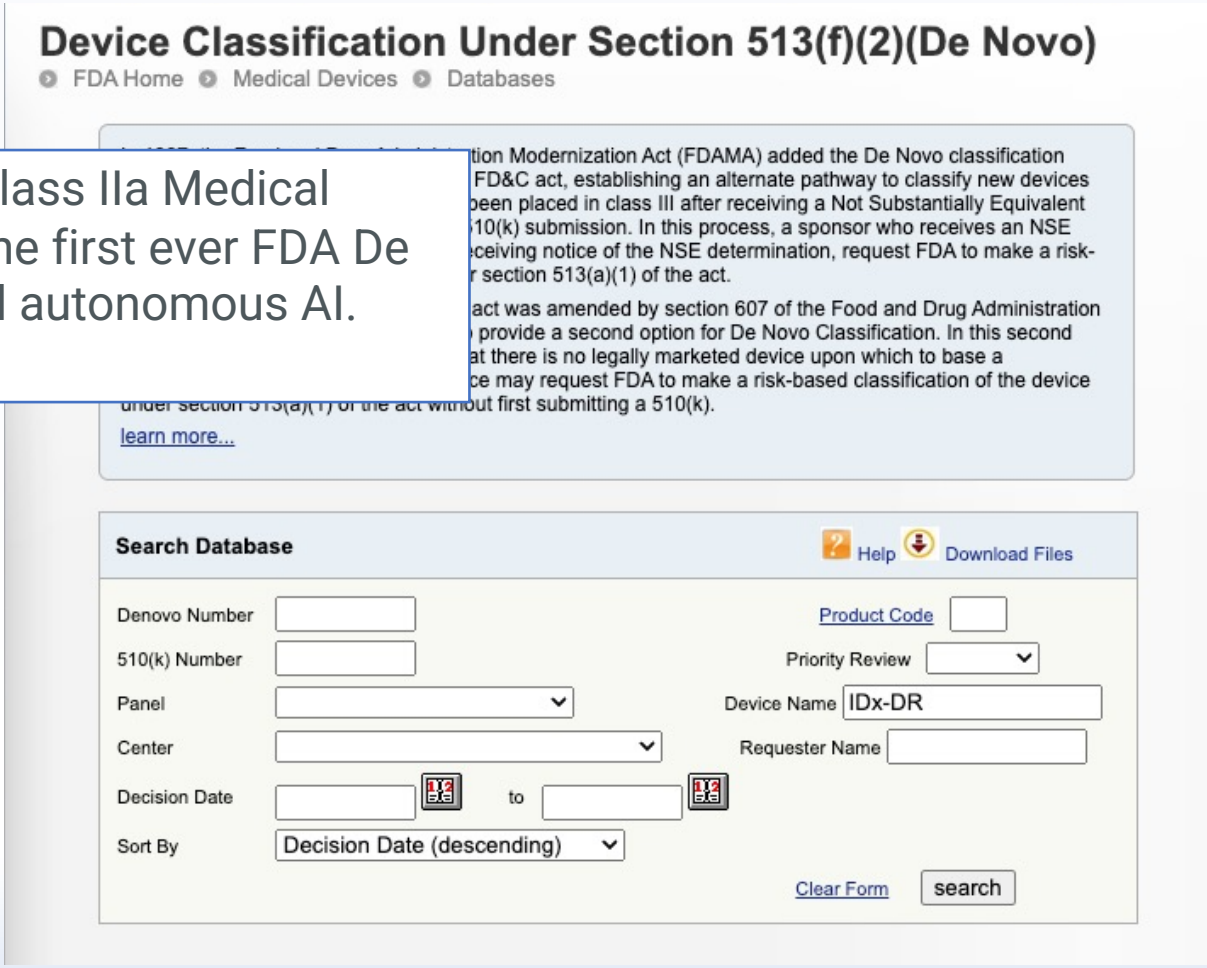
Software as a medical device products

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.



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
IDx-DR	IDx, LLC	DEN180001		04/11/2018

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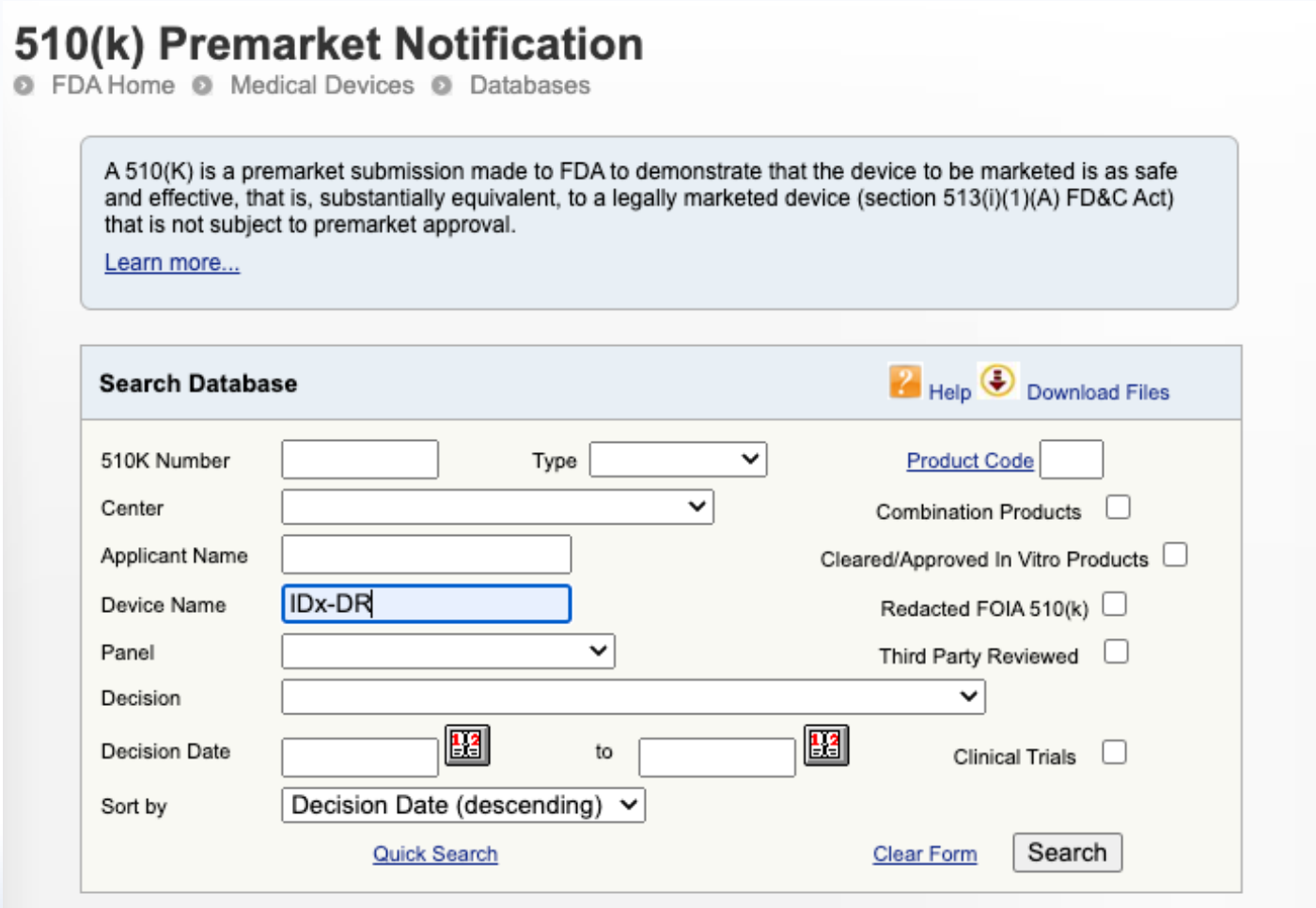
FDA approvals – 510(k)

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



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

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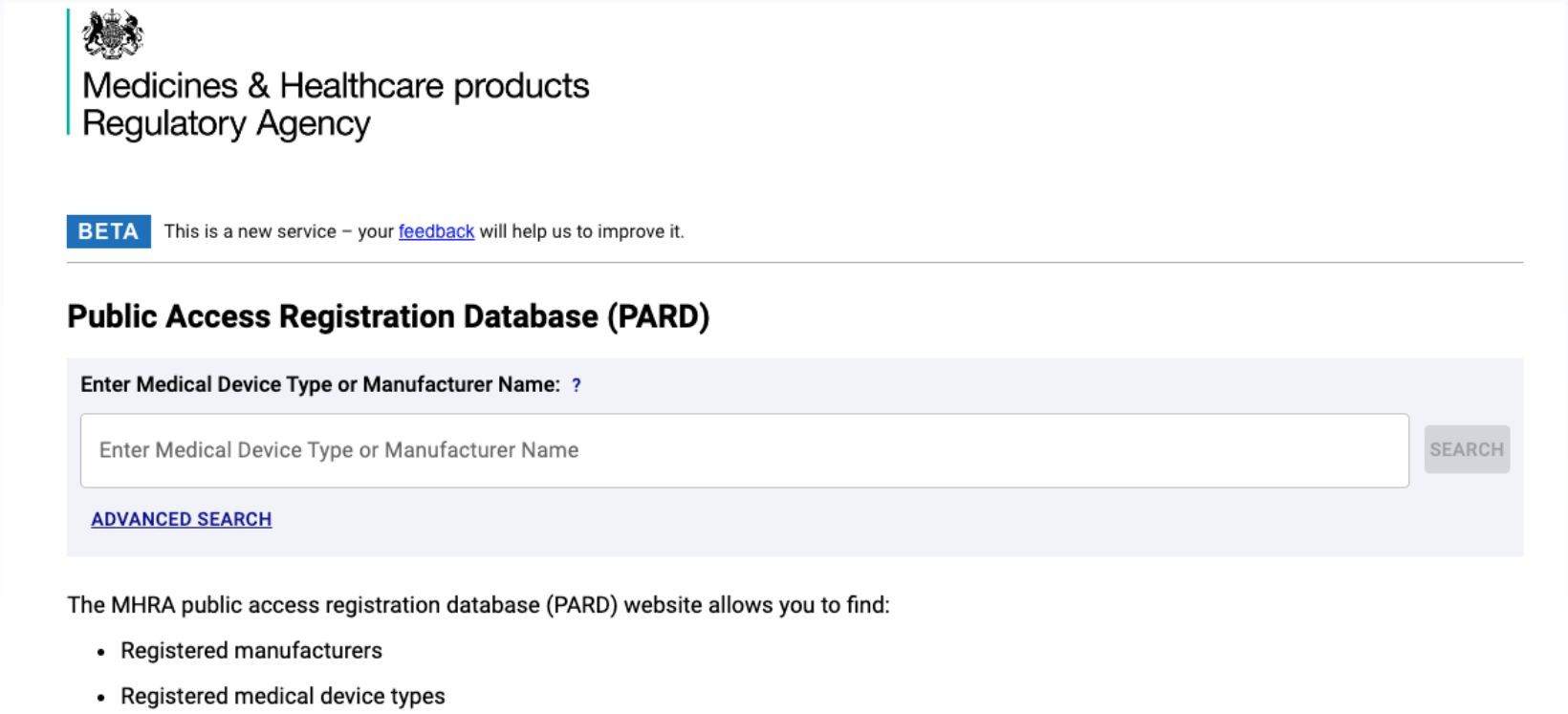
FDA approvals (cont.)

New Search | Back To Search Results

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

MHRA approvals

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



MHRA approvals (cont.)

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

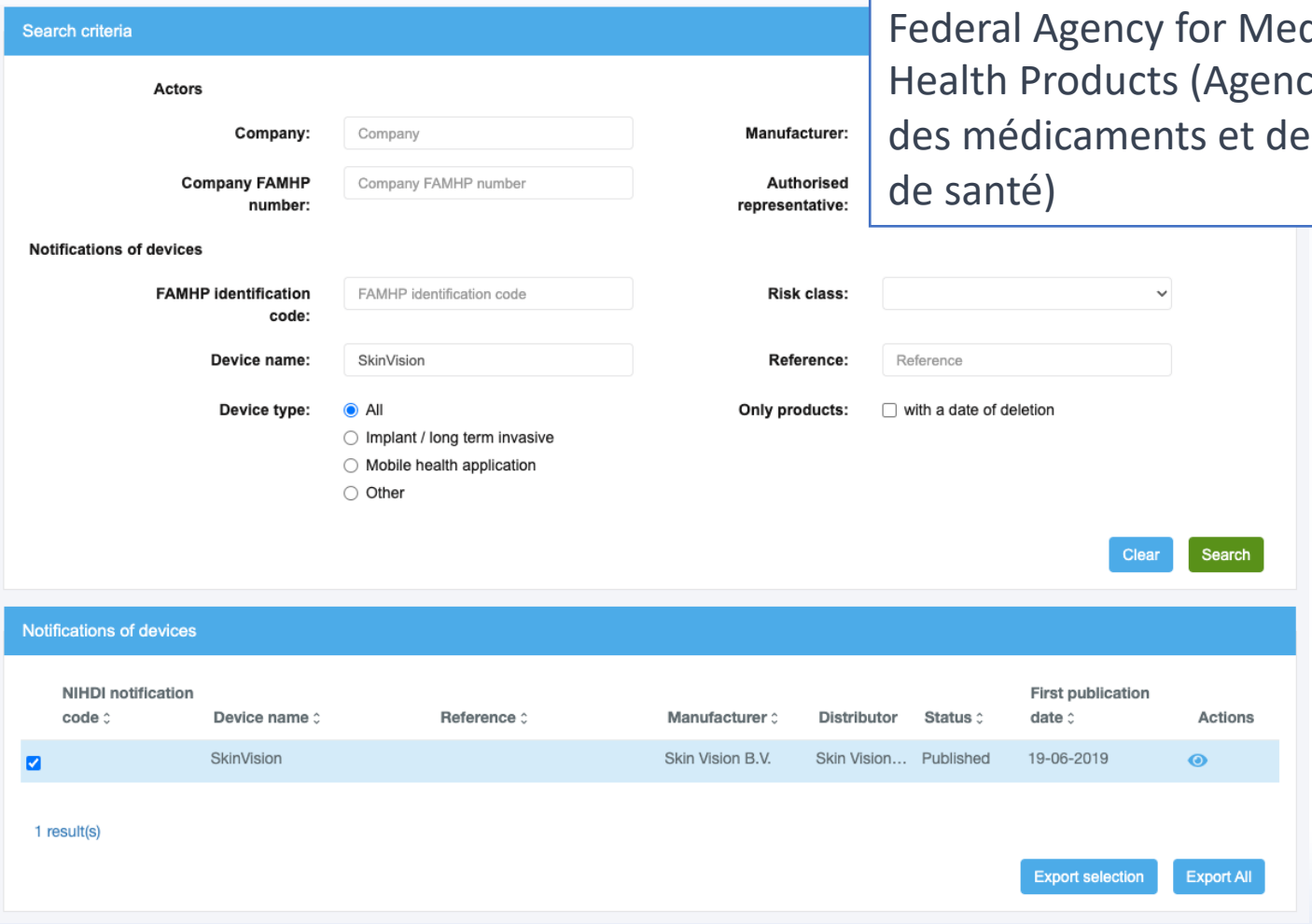
Relationship:
UK Responsible Person

Representative Address:
38 Queen Street
Glasgow
Scotland, United Kingdom
G1 3DX

FAMHP approvals

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

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



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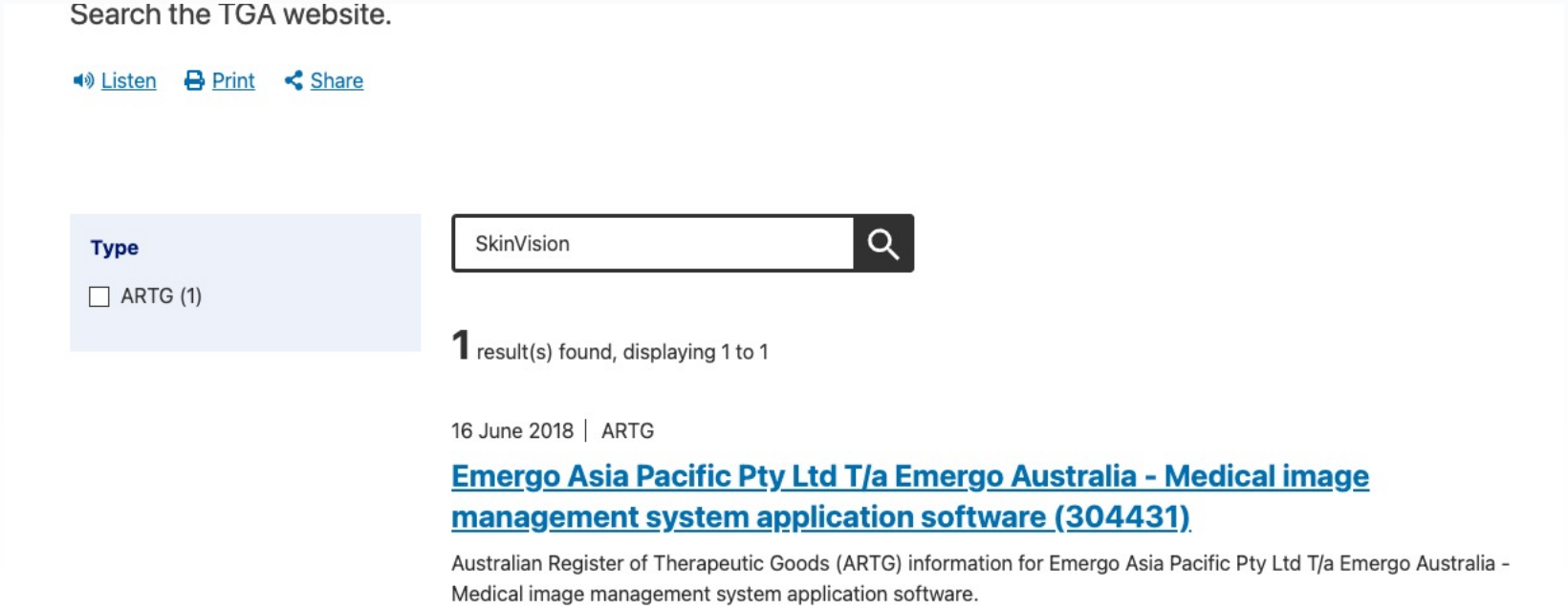
FAMHP approvals (cont.)

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:	www.skinvision.com
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

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



TGA approvals

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	Emergo Asia Pacific Pty Ltd T/a Emergo Australia
Manufacturers	SkinVision BV
Licence category	INC
Licence status	A
Licence class	Class 1
Summary	Download PDF

Scientific papers

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

Scientific papers (cont.)

PubMed.gov

IDx-DR[Title/Abstract] Search

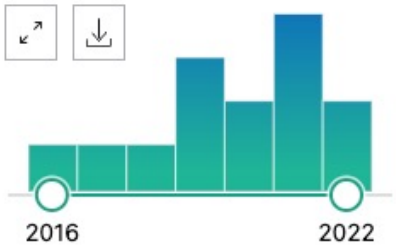
Advanced Create alert Create RSS User Guide

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 ATTRIBUTE

1 Cite Share

IDx-DR for Diabetic Retinopathy Screening.

Savoy M.

Am Fam Physician. 2020 Mar 1;101(5):307-308.

PMID: 32109029 **Free article.** No abstract available.

2 Cite Share

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

Grzybowski A, Brona P.

J Clin Med. 2021 May 27;10(11):2352. doi: 10.3390/jcm10112352.

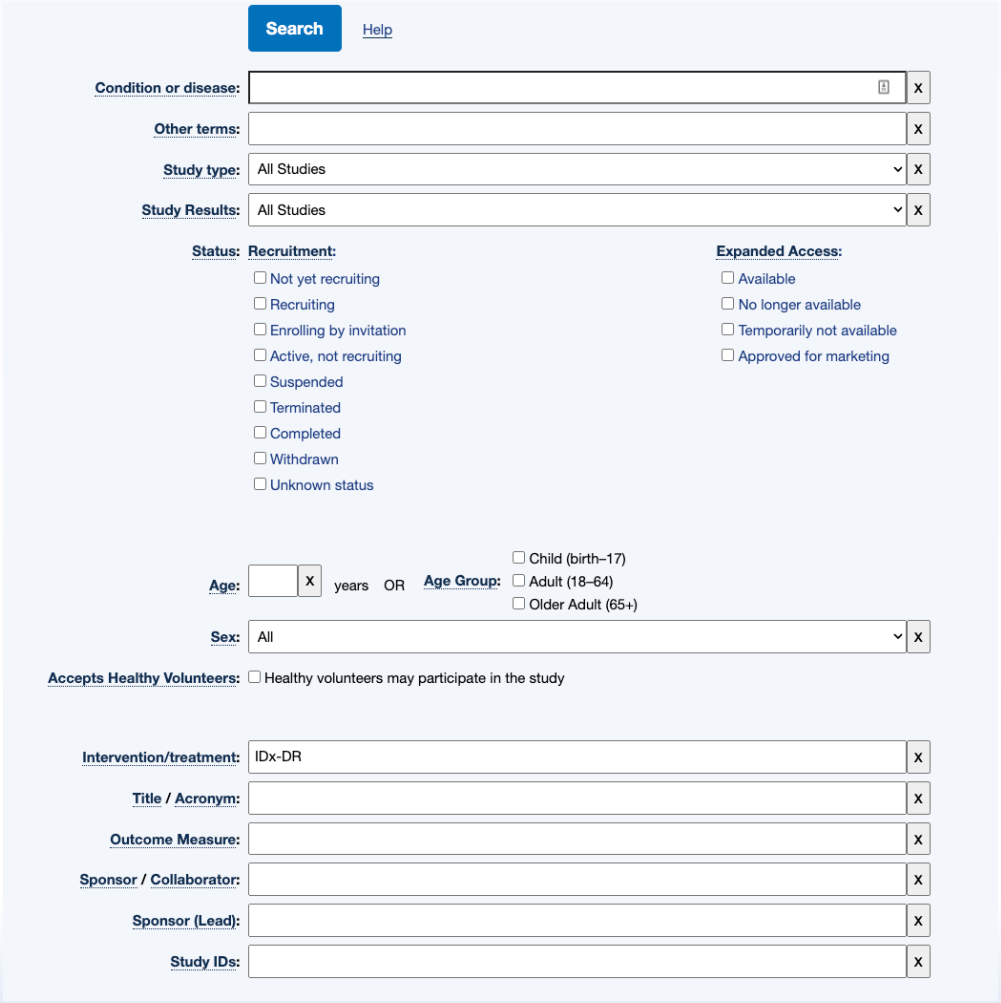
PMID: 34071990 **Free PMC article.**

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



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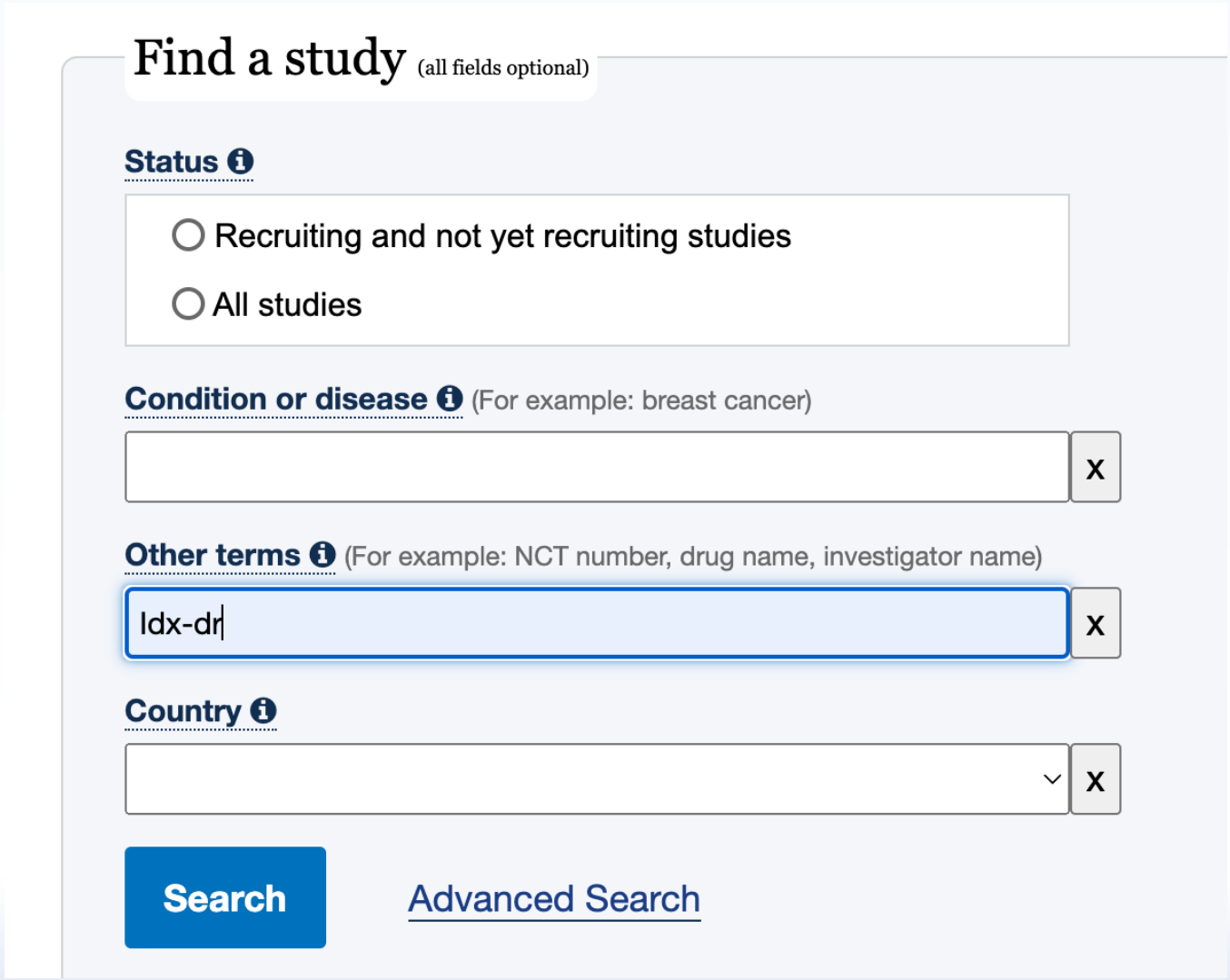
Clinical trials registry (cont.)

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Recruiting	ACCESS 2: AI for pediatriC diabetiC Eye examS Study 2	• Type 1 Diabetes • Type 2 Diabetes • Cystic Fibrosis-related Diabetes	• Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam	• Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States
2	☐	Completed	ACCESS: AI for pediatriC diabetiC Eye examS Study	• Type 1 Diabetes • Type 2 Diabetes	• Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam	• Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States
3	☐	Completed	Computer Detection of Diabetic Retinopathy Compared to Clinical Examination	• Diabetic Retinopathy	• Procedure: Photography of the retina • Procedure: Retinal photography	• Barnet Dulaney Perkins Eye Center Mesa, Arizona, United States • Barnet Dulaney Perkins Eye Center Phoenix, Arizona, United States • Iowa Eye Center Cedar Rapids, Iowa, United States • (and 4 more...)

Clinical trials registry (cont.)



Clinical trials registry (cont.)

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Completed Has Results	A Multi-center Study to Evaluate Performance of an Automated Device for the Detection of Diabetic Retinopathy	• Diabetic Retinopathy		
2	☐	Recruiting	ACCESS 2: AI for pediatriC diabetiC Eye examS Study 2	• Type 1 Diabetes • Type 2 Diabetes • Cystic Fibrosis-related Diabetes	• Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam	• Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States
3	☐	Completed	ACCESS: AI for pediatriC diabetiC Eye examS Study	• Type 1 Diabetes • Type 2 Diabetes	• Diagnostic Test: Point of Care Autonomous AI diabetic retinopathy exam	• Johns Hopkins Pediatric Diabetes Center Baltimore, Maryland, United States
4	☐	Completed	Computer Detection of Diabetic Retinopathy Compared to Clinical Examination	• Diabetic Retinopathy	• Procedure: Photography of the retina • Procedure: Retinal photography	• Barnet Dulaney Perkins Eye Center Mesa, Arizona, United States • Barnet Dulaney Perkins Eye Center Phoenix, Arizona, United States • Iowa Eye Center Cedar Rapids, Iowa, United States • (and 4 more...)

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Clinical trials registry (cont.)

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Recruiting	ARTIficial Intelligence-based Smartphone Application for Skin Cancer Detection	• Skin Cancer		• Department of Dermatology, Ghent University Hospital Ghent, East Flanders, Belgium
2	☐	Recruiting	Melanoma Detection in Switzerland With VECTRA	• Melanoma (Skin)	• Device: 3D imaging Total Body Photography Vectra® WB360 • Device: 2D imaging FotoFinder ATBM® Master imaging system • Device: Smartphone application (**SkinVision®**) • Other: Standard-of-care clinical assessment of the skin	• Department of Dermatology, University Hospital Basel Basel, Switzerland

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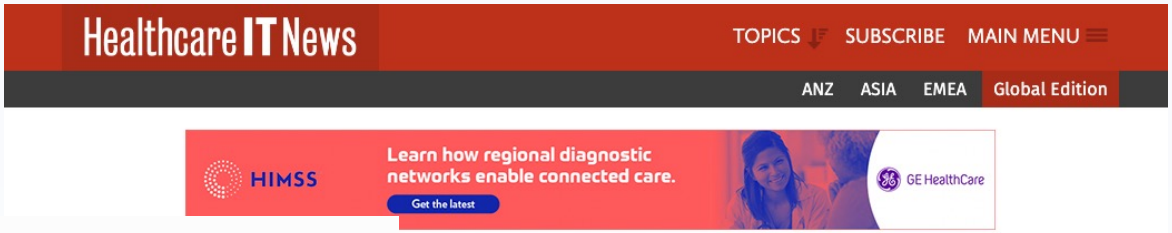
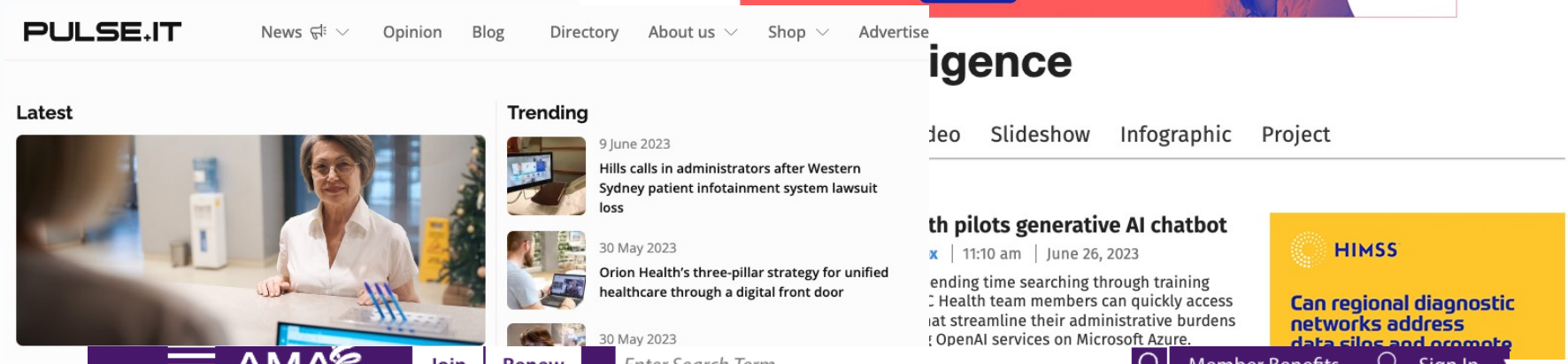
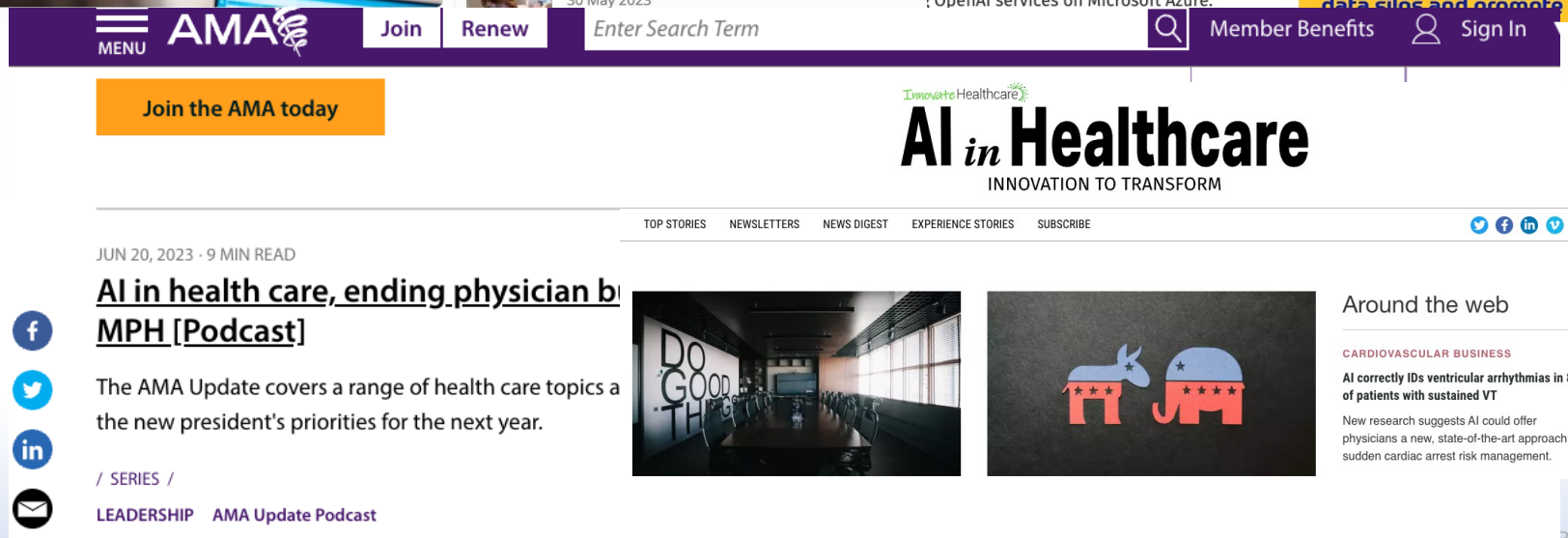
Other sources







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Not as SaMD

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

AI?

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