the royal victorian eye and ear hospital

Celebrating 160 years

November 2023

In Acknowledging Country we recognise and respect the culture, history and diversity of Australia's First Nation People

the royal victorian eye and ear hospital

Celebrating 160 years

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Workshop 1
AI and social media

View of apps as TGA regulatable in Trials

(issues to consider)

Forbes

FORBES > INNOVATION

10 Ways AI Is Advancing Healthcare

Ariel Katz Forbes Councils Member
Forbes Technology Council COUNCIL POST | Membership (Fee-Based)

Sep 19, 2023, 10:00am EDT

Ariel Katz, CEO and cofounder of H1.

GETTY

The explosion of generative AI in healthcare—largely due to the exponential growth of medical data, a shortage of healthcare providers and advancements in technology, according to the World Economic Forum (WEF)—holds so much promise. Though it may seem daunting,

Disclaimer: The views, thoughts, and opinions expressed in this presentation belong solely to the author, and not necessarily to the author's employer, organisation, committee or other group or individual.

Artificial Intelligence

- HAL 9000 (or simply HAL or Hal) is a fictional artificial intelligence character and the main antagonist in Arthur C. Clarke's Space Odyssey series. First appearing in the 1968 film 2001: A Space Odyssey, HAL (Heuristically Programmed Algorithmic Computer) is a sentient artificial general intelligence computer that controls the systems of the Discovery One spacecraft and interacts with the ship's astronaut crew.

- HAL is listed as the 13th-greatest film villain in the AFI's 100 Years...100 Heroes & Villains.

What is artificial intelligence?

- Artificial intelligence (AI) is computer software that mimics human cognitive abilities in order to perform complex tasks that historically could only be done by humans, such as decision making, data analysis, and language translation.

- AI is code on computer systems explicitly programmed to perform tasks that require human reasoning.

- While automated machines and systems merely follow a set of instructions and dutifully perform them without change, AI-powered ones can learn from their interactions to improve their performance and efficiency.

- Machine learning, meanwhile, is a subset of AI that uses algorithms trained on data to produce models that can perform such complex tasks.

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Regulation of software based medical devices

Clinical Trials

Peter Keller

Regulation of Therapeutic Goods

- **Therapeutic Goods Act 1989**

- The TGA regulates therapeutic goods in Australia, medicinal products and biologicals under the TG Regs 1990 and medical devices under the TG (Medical Devices) Regs (2002) and other legislative instruments.

- A software product meets the definition of a medical device if it falls within the definition of a medical device (under s41BD of the TG Act). It is the responsibility of the manufacturer to determine if the product is a medical device.

- If a software product is a medical device it must be included in the ARTG, unless it is exempt, before it can be legally supplied in Australia.

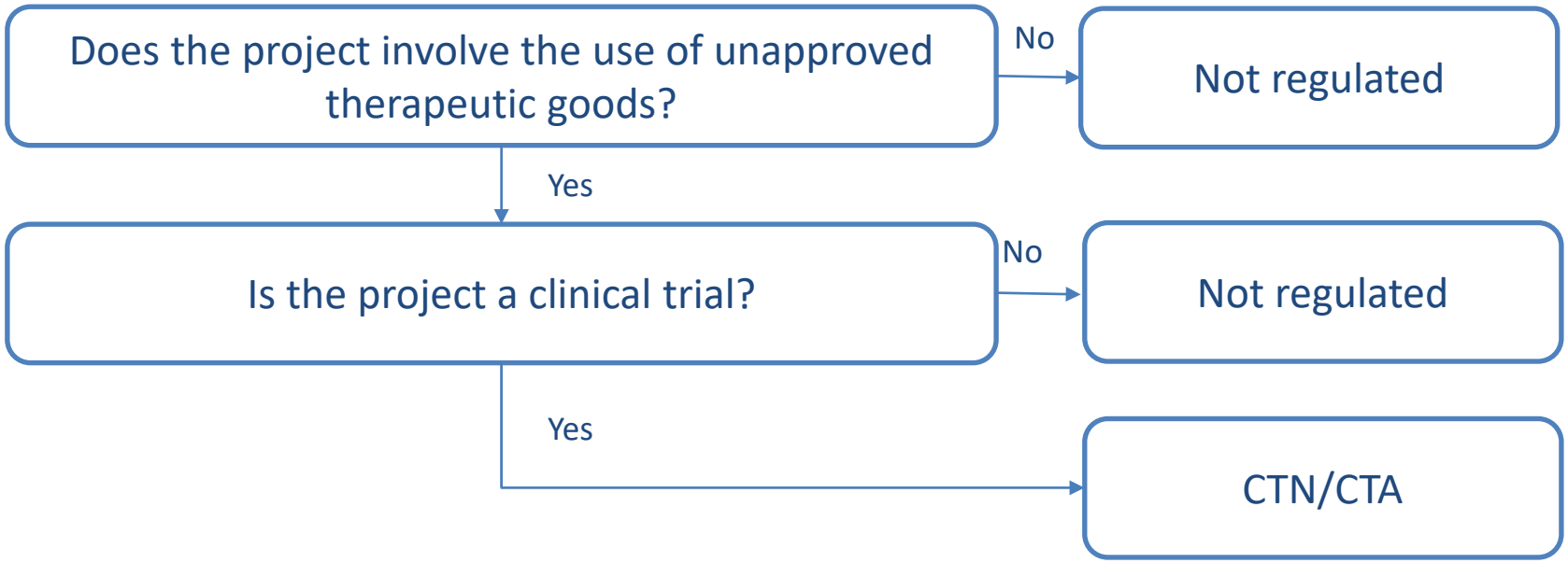
- One such exemption is 19(1)(b) for use solely for experimental purposes in humans”

Regulation of Therapeutic Goods

Under the CTN and CTA schemes significant responsibility is devolved to the reviewing HREC(s) for assessing the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good(s), the overall ethical acceptability of the trial, approval of the trial protocol, and monitoring* the conduct of the trial.

Only some software is regulated by the TGA

Is the research proposal a clinical trial involving therapeutic goods?



Software based medical devices

- are medical devices that incorporate software or are software, including software as a medical device, or software that relies on particular hardware to function as intended, and are regulated in Australia by the TGA. Software (including mobile apps) is a medical device if it fits within the definition of a medical device in section 41BD of the *Therapeutic Goods Act 1989*, unless otherwise excluded.

- Many mobile apps are simply sources of information, or tools to manage a healthy lifestyle. The TGA does not regulate health and lifestyle apps or other software that does not meet the definition of a medical device.

Some examples of software or apps that **are** medical devices are:

- An app that organises and tracks a person's health information, and analyses this information to diagnose diabetes, or provide a percentage risk of the user having diabetes.
- Software that analyses skin images to screen for melanoma

Recent reforms have been implemented to clarify the requirements of regulated software based medical devices, including introducing a number of exclusions and exemptions for specific types of software products:

- **Excluded products are not medical devices, and are not subject to any TGA regulatory requirements.**
- **Exempt software is a medical device, but is not subject to all regulatory requirements.**

Upcoming guidance on **Clinical Decision Support Software** will provide detailed guidance on the exemption, including which products are covered, and which requirements still apply.

EXCLUSION

means that the devices are completely unregulated by TGA

EXEMPTION

means that TGA retains some oversight for advertising, adverse events and notification

Registration of the device is not required

Software as a Medical Device (SaMD)

Refers to software that can function on a laptop, smartphone or tablet, and has an **intended purpose** consistent with the definite of a medical device.

Intended purpose

- diagnosis, prevention, monitoring prediction, prognosis or treatment of a disease, injury, or disability
- compensation for an injury or disability
- investigation of the anatomy or of a physiological process
- to control conception

Some SaMD may be an accessory to a medical device. Accessories are regulated as separate medical devices.

Software that is part of a Medical Device (SiMD)

Software can be part of a medical device when it is integral to the functioning of that device, sometimes referred to as software in a medical device and is usually supplied with the hardware device.

SiMD is regulated as part of that device.

Example: Embedded software or firmware in a cardia pacemaker is regulated as a component of the pacemaker, because it is supplied as part of the device and is necessary for the device to operate.

Software that controls a Medical Device

Software, including mobile apps, can control or adjust a medical device through a connection, either physical or utilising wireless technology such as Bluetooth or WiFi.

Where software drives or influences a medical device, the software has the same **classification** as the medical device.

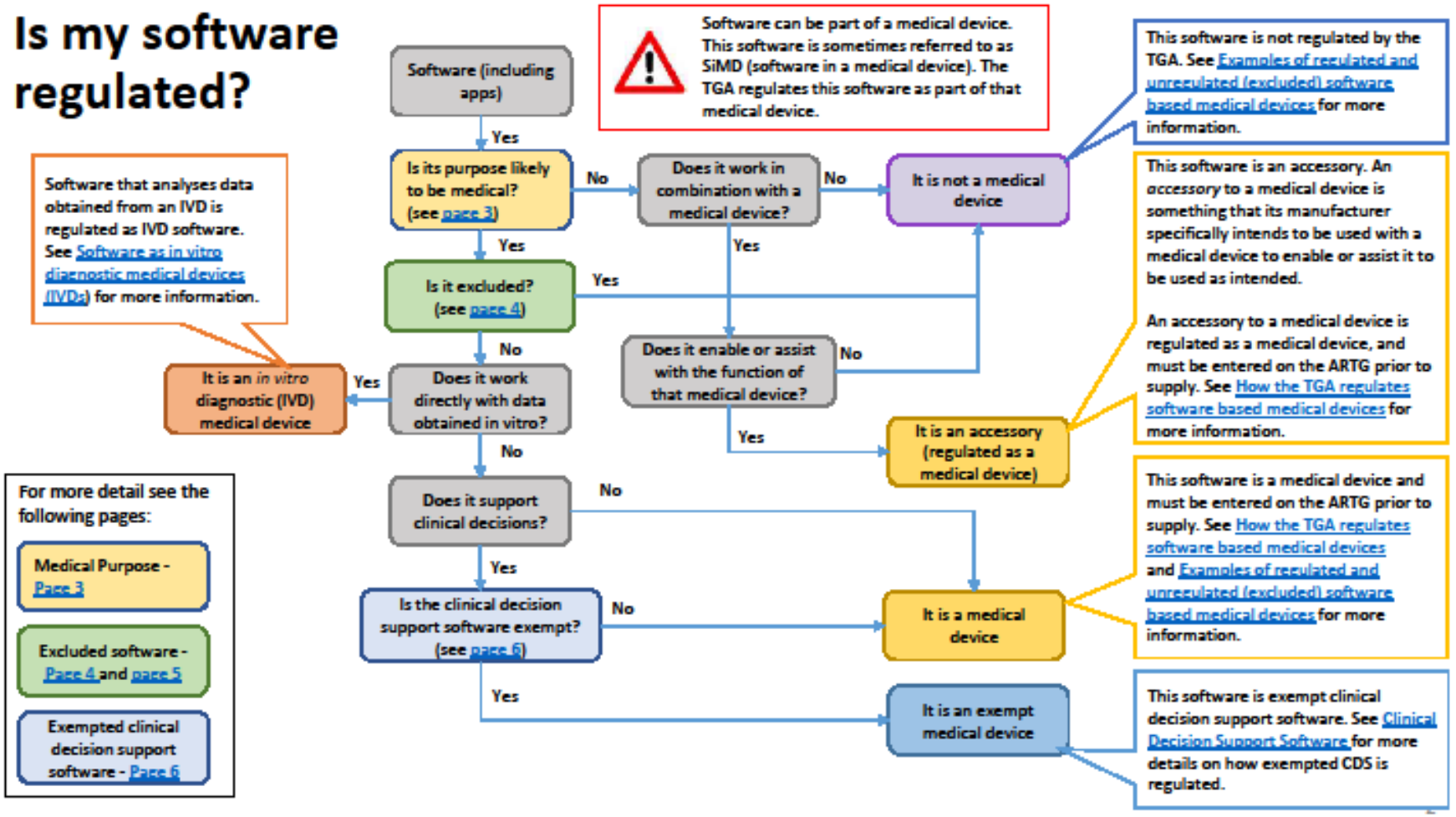
Software or an accessory to a medical device is a medical device in its own right if it is supplied separately from the related device.

Examples:

Pacemaker programmer and controller software for use on a PC or laptop.

An instance of cochlear implant configuration/optimisation software for use on a PC or laptop.

Is my software regulated?



Is its purpose likely to be medical?

Therapeutic Goods (Medical Devices) Regulations 2002
Intended purpose what the manufacturer intends it to be used for. This is usually described in:

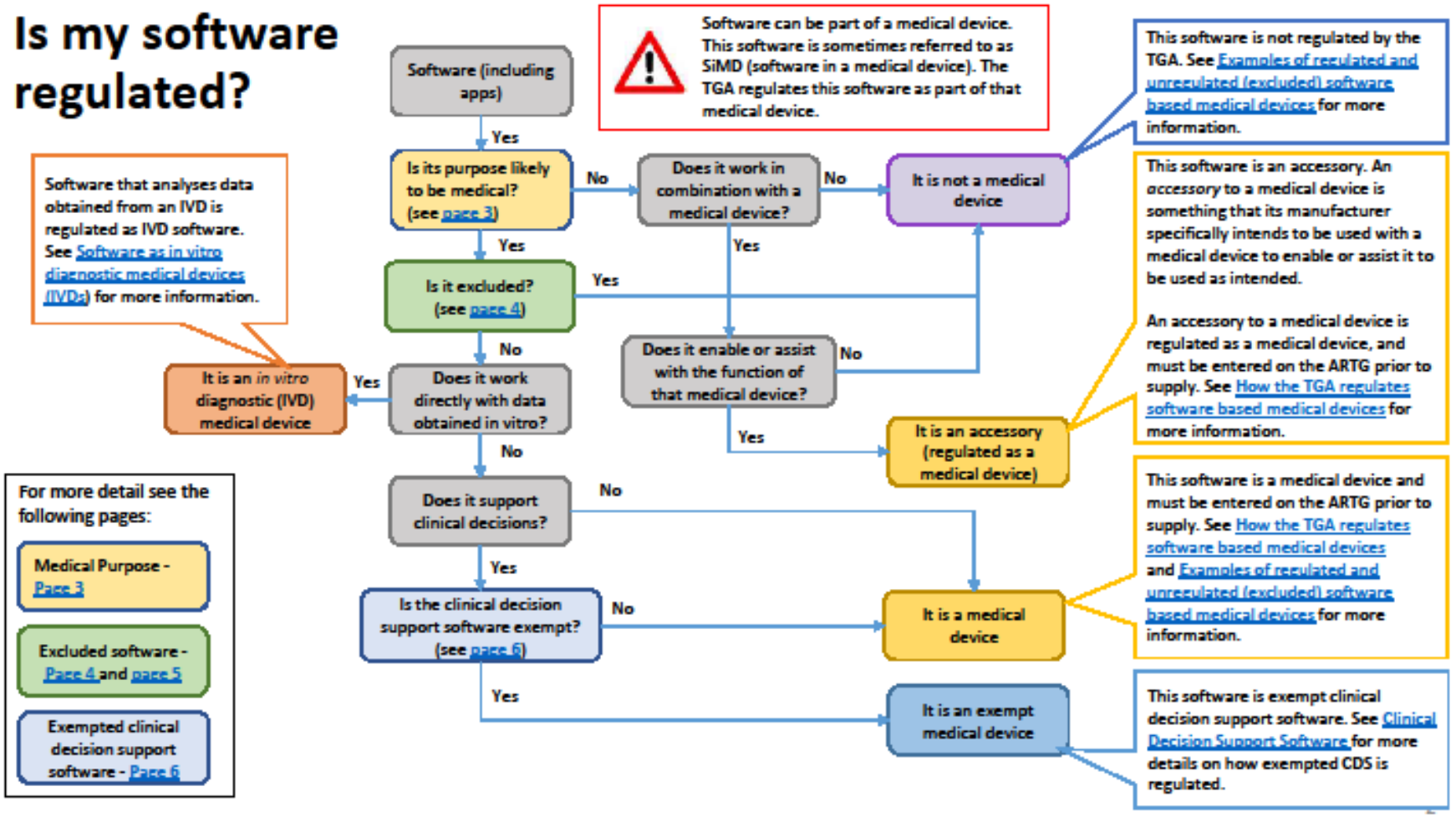
(a) information provided with the device; or
(b) instructions for use; or
(c) any advertising material; or
(d) any technical documentation.

The **intended purpose** of the software includes one or more of the following;
Diagnosis, monitoring, predication, prognosis, treatment or alleviation of disease, injury or disability
Prevention of disease
Compensation for an injury or disability
Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
Control or support of conception

→ No

Yes

Is my software regulated?



Is it excluded?

Does it have any of these functions ?
Consumer health products – prevention, management and follow up devices that do not provide specific treatment or treatment suggestions
Digital Mental Health
Enabling technology intended to support telehealth, remote diagnosis, healthcare or dispensing
Digitisation of paper based or other published clinical rules or data including simple dose calculators and Electronic Patient Records
Population based analytics that do not drive outcomes for individuals
Laboratory Information Management Systems – systems to automate workflows, integrate instruments, manage orders and samples and associated information

Therapeutic Goods (Excluded Goods) Determination 2018.
Software limited to performing certain functions has been excluded from regulation

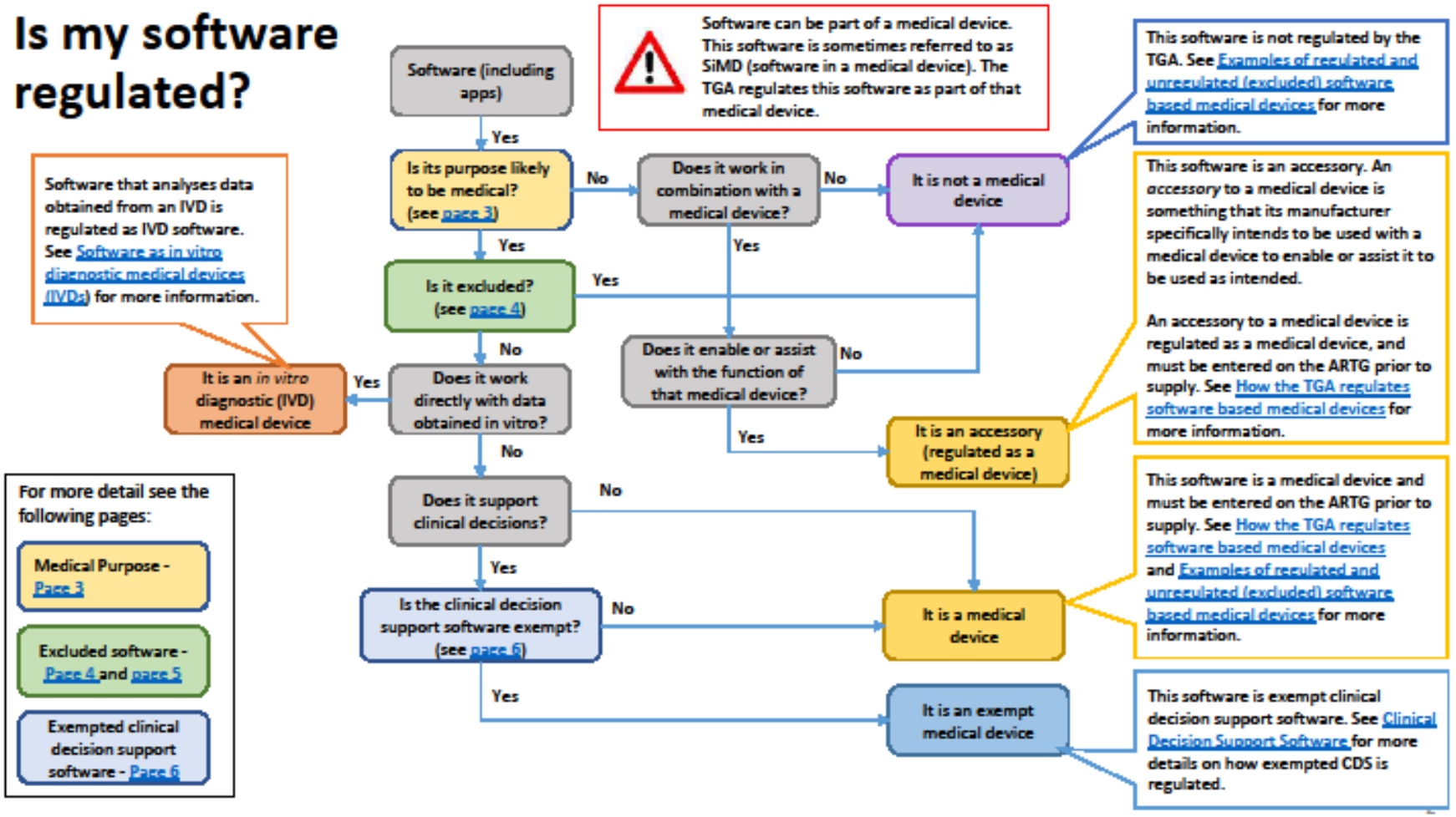
Yes

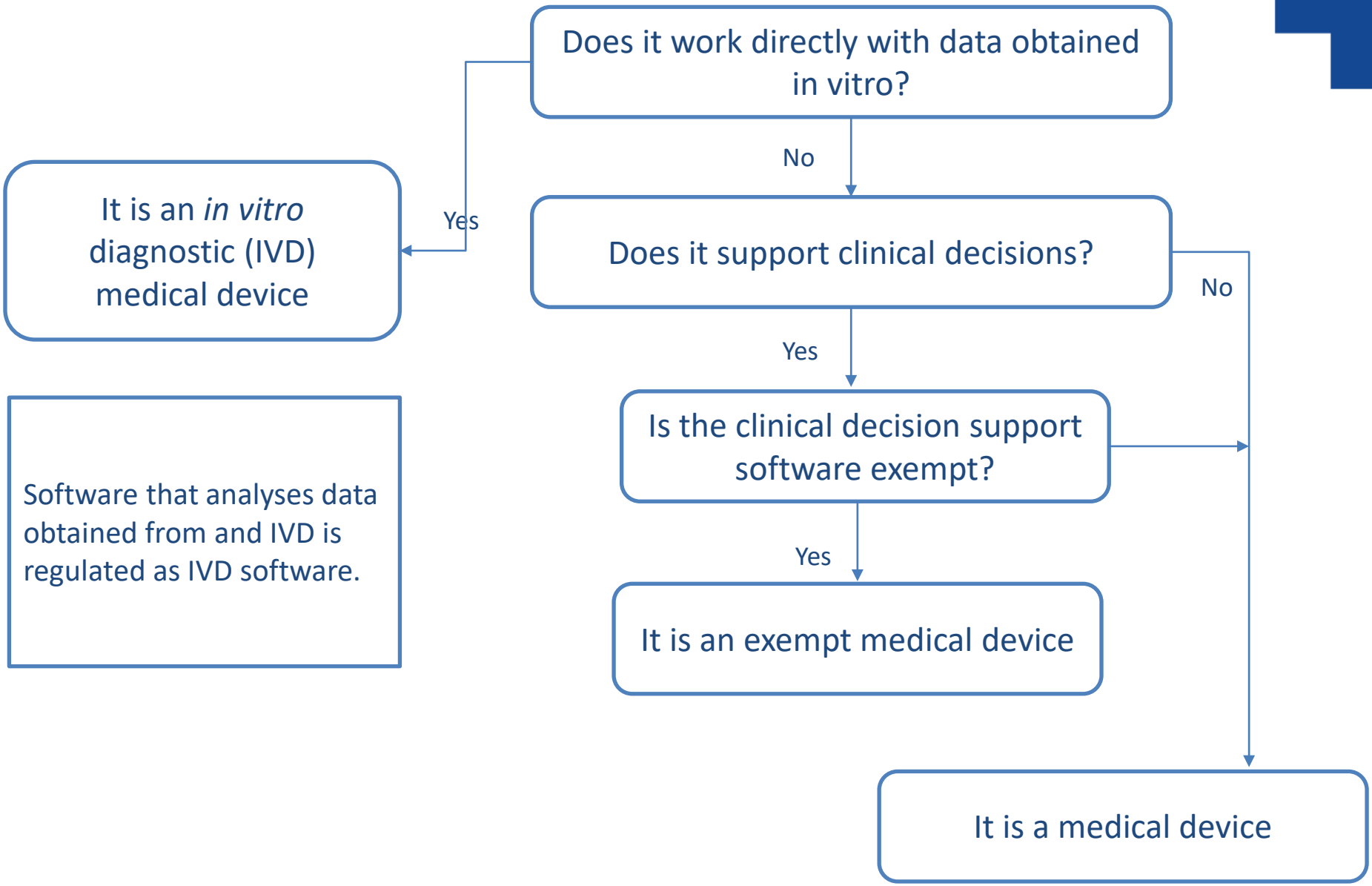
It may be excluded

No

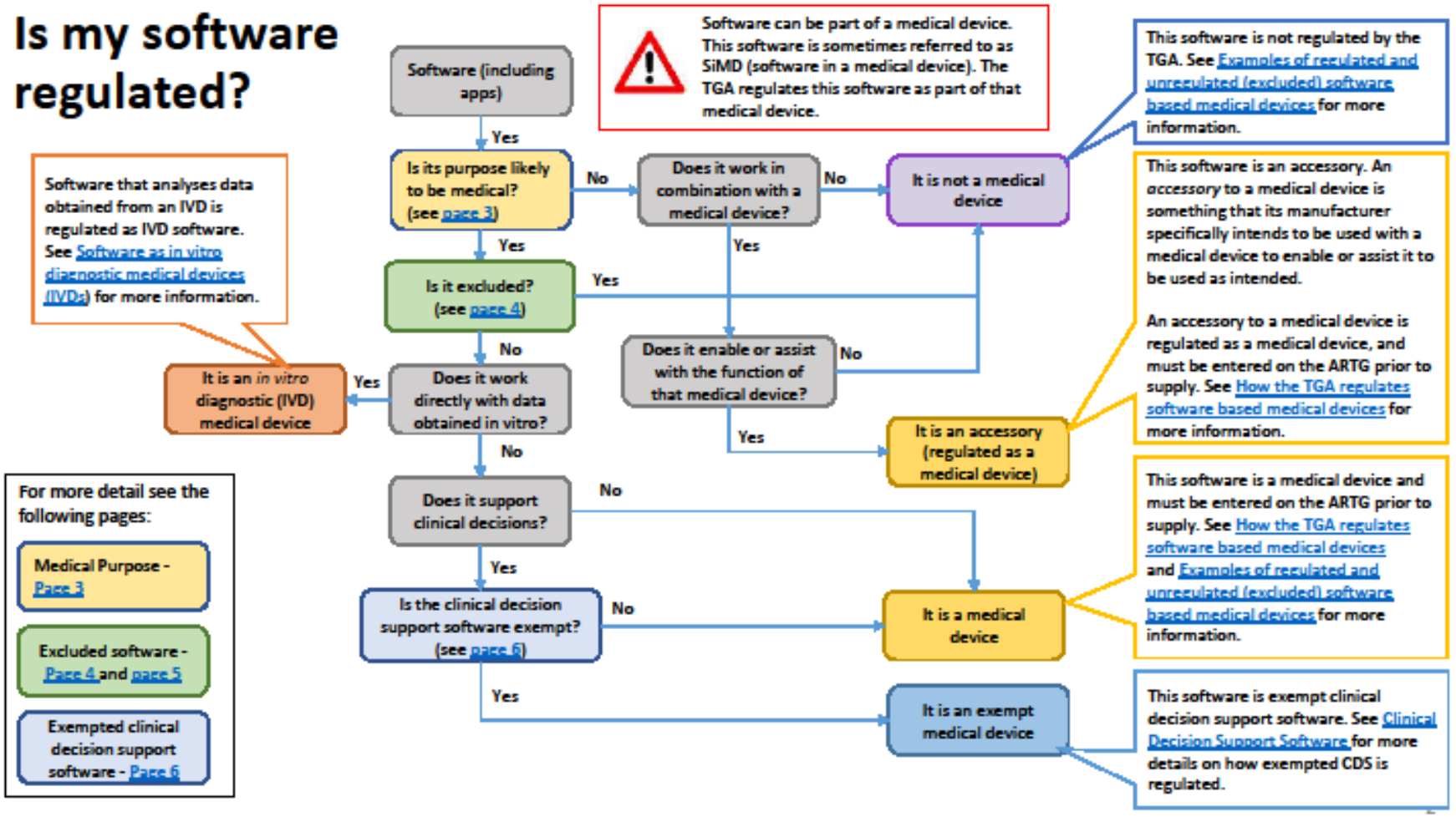
No, it is not excluded

Is my software regulated?




Does it work directly with data obtained in vitro?
Yes
It is an *in vitro* diagnostic (IVD) medical device
No
Does it support clinical decisions?
No
Yes
Is the clinical decision support software exempt?
Yes
It is an exempt medical device
It is a medical device
Software that analyses data obtained from and IVD is regulated as IVD software.

Is my software regulated?



Is the clinical decision support software exempt?

Therapeutic Goods (Medical Devices) Regulations 2002.
Software medical devices are exempt from the requirement to be entered on the ARTG.
Exempt devices must still comply with certain regulatory requirements.

Does the clinical decision support software meet **all 3** of these criteria?

Yes

It is not intended to directly process or analyse a medical image or a signal from another medical device (including an IVD medical device); and

No

Yes

It is intended only for the purpose of providing or supporting a recommendation to a health professional about prevention, diagnosis, curing or alleviating a disease, ailment, defect or injury: and

No

Yes

It is intended only for the purpose of providing or supporting a recommendation to a health professional about prevention, diagnosis, curing or alleviating a disease, ailment, defect or injury: and

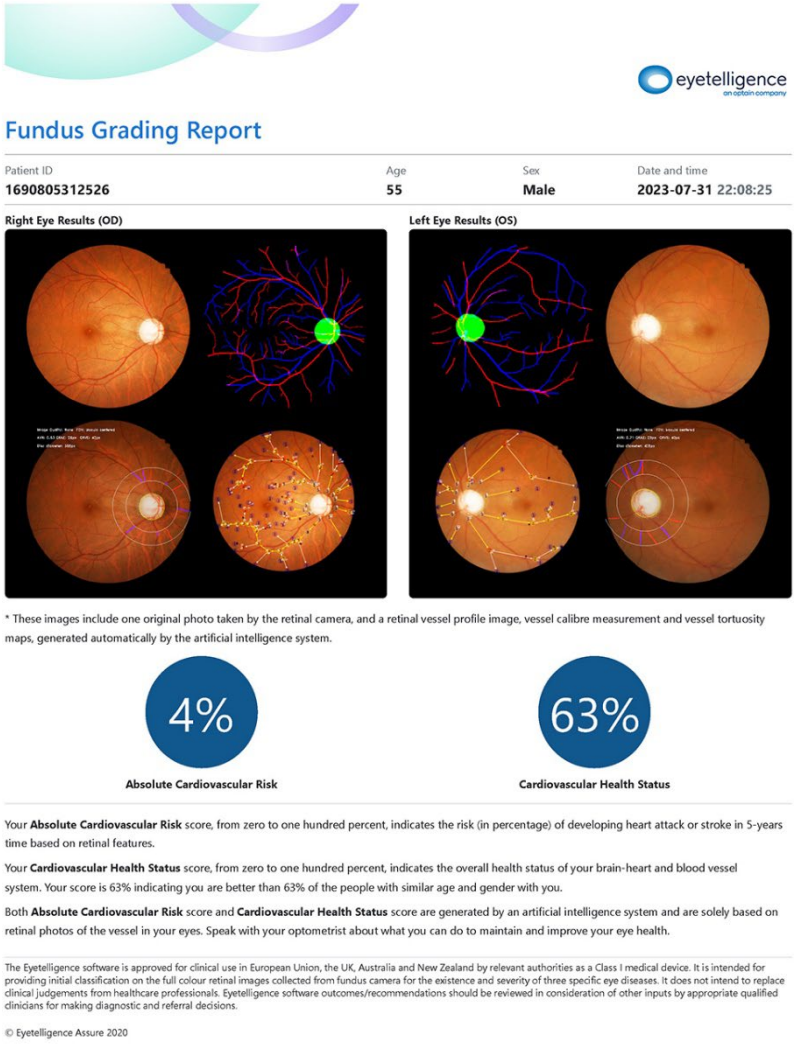
No

Yes

It is an exempt medical device

Eyetelligence

The Eyetelligence software is approved for clinical use in European Union, the UK, Australia and New Zealand by relevant authorities as a Class I medical device. It is intended for providing initial classification on the full colour retinal images collected from fundus camera for the existence and severity of three specific eye diseases. It does not intend to replace clinical judgements from healthcare professionals. Eyetelligence software outcomes /recommendations should be reviewed in consideration of other inputs by appropriate qualified clinicians for making diagnostic and referral decisions.



eyetelligence
an optain company

Fundus Grading Report

Patient ID	Age	Sex	Date and time
1690805312526	55	Male	2023-07-31 22:08:25

Right Eye Results (OD)

Left Eye Results (OS)

* These images include one original photo taken by the retinal camera, and a retinal vessel profile image, vessel calibre measurement and vessel tortuosity maps, generated automatically by the artificial intelligence system.

4%

Absolute Cardiovascular Risk

63%

Cardiovascular Health Status

Your **Absolute Cardiovascular Risk** score, from zero to one hundred percent, indicates the risk (in percentage) of developing heart attack or stroke in 5-years time based on retinal features.

Your **Cardiovascular Health Status** score, from zero to one hundred percent, indicates the overall health status of your brain-heart and blood vessel system. Your score is 63% indicating you are better than 63% of the people with similar age and gender with you.

Both **Absolute Cardiovascular Risk** score and **Cardiovascular Health Status** score are generated by an artificial intelligence system and are solely based on retinal photos of the vessel in your eyes. Speak with your optometrist about what you can do to maintain and improve your eye health.

The Eyetelligence software is approved for clinical use in European Union, the UK, Australia and New Zealand by relevant authorities as a Class I medical device. It is intended for providing initial classification on the full colour retinal images collected from fundus camera for the existence and severity of three specific eye diseases. It does not intend to replace clinical judgements from healthcare professionals. Eyetelligence software outcomes/recommendations should be reviewed in consideration of other inputs by appropriate qualified clinicians for making diagnostic and referral decisions.

Eyetelligence

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355170	Eyetelligence Pty Ltd - Automated retinopathy analysis system application software
ARTG entry for	Medical Device Included Class 1	
Sponsor	Eyetelligence Pty Ltd	
Postal Address	1101 442 St Kilda Road, Melbourne, VIC, 3004 Australia	
ARTG Start Date	18/02/2021	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Eyetelligence Pty Ltd	1101 442 St Kilda Road Melbourne, VIC, 3004 Australia

Products

1 . Automated retinopathy analysis system application software

Product Type	Single Device Product	Effective Date	18/02/2021
GMDN	58713 Automated retinopathy analysis system application software		
Intended Purpose	The Eyetelligence Advanced Vision is a Software as a Service product based on computer vision and natural language processing technology. This product intends to automatically provide information on the imaging modalities that used to generate the image and screen for diseases that is most consistent with the features of the images and the pathologic lesions existed in the image. The Eyetelligence system outcomes are intended to be subsequently verified and certified by a qualified medical/eye care professional who will make a clinical decision based on a range of inputs not limited to Eyetelligence outcomes.		

Specific Conditions

No Specific Conditions included on Record

Public Summary