Commercially available

Smart eye camera attached to a smartphone*

Country of origin | Japan

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 1000

Year of commercialization: 2021

Number of units distributed: 250

Currently marketed in: Belgium, Cambodia, Germany, Japan, Kenya, Spain and Viet Nam

Model: Smartphone attachment medical device

Product description

Smart Eye Camera (SEC) is a smartphone attachment medical device that uses the light source and camera function of the smartphone, enabling it to observe the anterior segment of the eye with equal function to the conventional slit-lamp microscope. By attaching the SEC to a smartphone, the user can observe the eyelid, cornea, anterior chamber, iris, lens, and vitreous body, as with existing slit-lamp microscopes, and diagnose ophthalmic diseases such as cataracts.

Product details

Accessories: The device is applicable to iPhone 7/8/SE2/SE3. The device is delivered with the applicable phones with the software (SEC App) installed and the charger of the iPhone and the hard-case for the device.

Consumables: n/a

Warranty duration: 2 years

Lifetime: 5 years

Energy requirements: No. No need for external battery as long as the phone is charged.

Facility requirements: Please store in the attached case in a stable place. Carry by putting it in the attached case. Store under the following environment: Temperature: 4-35°C; Humidity: 30–80% RH (no condensation of moisture); Atmospheric pressure: 800–1060 hPa; Avoid direct sunlight, store at a place away from any liquid; store away from flammable fumes/liquid.

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*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Preventable blindness is one of the major public health challenges faced today. In low-resource settings, access to adequate ophthalmic care is hindered by the low availability of adequate equipment and trained professionals, delaying diagnosis and referral.

The slit-lamp microscope is an essential tool in ophthalmic examination. However, it is a cumbersome, sensitive, and costly piece of equipment. Moreover, most slit-lamp microscopes cannot acquire images (photography or video).

This technology simplifies several aspects of the slit-lamp microscope examination. It is a compact device that transforms a smartphone into a device capable of performing a comprehensive examination of the anterior structures of the eye. Through the smartphone's capabilities, it is also possible to record and transmit videos to other health-care professionals at different locations. This device has been field-tested for use in the diagnosis of dry eye disease and cataracts. It may also assist in the diagnosis of trachoma, traditionally diagnosed with the use of loupes.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

This medical device is an ophthalmic camera that is applied to mobile phones to diagnose specific ophthalmic clinical issues. A slit lamp, whose specifications are not included in any technical requirements document, WHO or UNICEF catalogues, is the medical equipment with the more comparable technical requirements. Consequently, at the time of this report creation, WHO and/or UNICEF technical specifications were not available to compare this type of technology.

Regulatory

Pre-market: This product is a Class I medical device in Japan and has obtained market approval in Cambodia, the EU, Japan, Kenya, Viet Nam and Swissmedic Class I notification. However, the manufacturer did not provide adequate documentation for a regulatory review, including the design verification reports and the validation test reports lists.

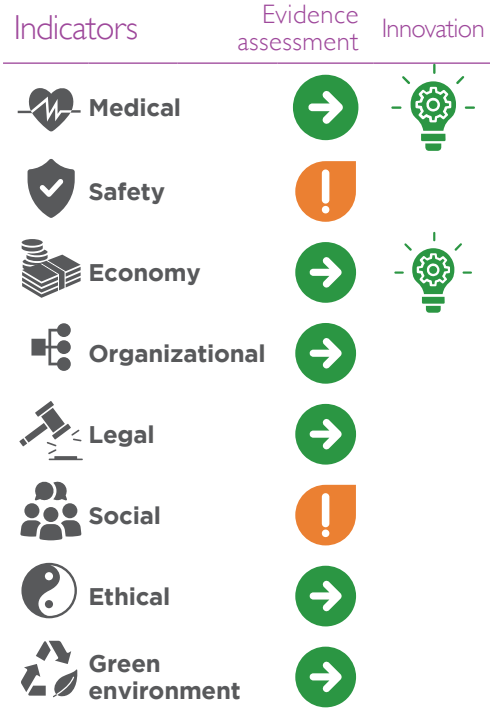
Post-market: The manufacturer did not submit surveillance and vigilance documentation, complaint handling, field safety corrective action, recall, or adverse event reporting documents.

Quality management system (QMS): The manufacturer has submitted a valid ISO13485:2016 which is valid until 13 June 2026. Based on the certification and standards, the manufacture of the product conforms to ISO13485:2016. Based on the certification and standards for the performance of this device, the documentation submitted is not adequate to demonstrate that the product is safe and effective.

Security: Introduction of this technology would not lead to cybersecurity or biosecurity risk. The manufacturer did not submit risk management documentation, risk analysis, risk management plan, risk control, post-production information, or other hazard reports.

Adequate documentation was not provided to perform a medical device regulatory premarket, post-market, quality system, and security review and assessment on the product to demonstrate that the product is safe and performs as intended by the manufacturer.

Health technology assessment



The technology is non-invasive and uses the light source and the camera of a smartphone to deliver ophthalmic diagnosis, while not introducing any additional safety risk. However, although the innovator claims that the product is CE-certified, the documentation provided does not prove that. The two certificates provided, for risk and quality management, are issued to another company and not to the innovator, and it is not clear how the two companies are related. Despite the insufficient evidence, the technology may be considered safe, as there are no apparent reasons to the contrary. The associated risks are low, especially because it does not require an external power supply. The expected clinical benefits are high since it will enable non-ophthalmologists, nurses, and other health-care workers with no specific experience in ophthalmology to take good-quality ophthalmic images that can satisfy professional ophthalmologists, just after a short tutorial session. It is expected to play a critical role in improving the standard quality of ophthalmic services. The device is 80-90% less expensive than a conventional slit-lamp microscope and can extend the reach of accessible eye care.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

This product is app-based, with a base technology that is known and easy to use for everybody and requires use of proprietary 3D printed hardware and a commercially available iPhone. Currently, it is only available for IOS. It is 4-5 times more affordable than the standard of care technology. It is designed for basic ophthalmologic diagnosis in low-resource settings, allowing real-time contact with specialists when necessary, and does not require the heavy, expensive technology for routine eye checks.

Durability depends on the phone hardware. Because of the SEC lens attachment, a phone protective case cannot be used, and the device should be safely stored in the included storage case when not in use. Preventive maintenance is easy to provide to the supplied SEC hardware, and suppliers can be contacted electronically for support and parts. The phone requires maintenance at a specialized phone maintenance shop, which is usually easily available. Also, the manufacturer can provide repairs on the phone. Reparability does not only depend on the supplier, but also the phone manufacturer; the device will work properly as long as Apple keeps parts available. The supplier should keep their software up-to-date with IOS new releases to avoid crashes.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyright, patents and registered trademarks. Some patents are pending, and trade secrets are likely to exist. The use of all intellectual property will require clearance.

Local production: Only the SEC slit lamp attachment is considered (the mobile phone is excluded from the scope of evaluation for local production).

This is a potential product for local production. Although the company has product patents, there is insufficient evidence to ensure the manufacture of a safe medical device such as a fully compliant product design procedure and a fully compliant ISO 13485 QMS is not available. Further, low regional market demand, dependence on imported raw materials, machinery, and 3D Printer utilization scenario are unlikely to justify the business case for local production of this technology.