510(k) Summary

K190786

21 CFR 807.92

I. Submitter

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II. Proposed Device

Trade Name: Eye Prime

Manufacturer: Ellex Medical Pty Ltd

Common or Usual Name: Diagnostic ophthalmic ultrasound system

Classification:

Name	21 CFR Number	Product Code
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

III. Legally marketed Device /Predicate Device

Device name: Eye Cubed Version 4 Diagnostic Ultrasound

Premarket Notification: K103608

Manufacturer: Ellex Innovative Imaging

IV. Device Technological characteristics

The Eye Prime is a new, diagnostic ophthalmic ultrasound Track 1 device. Its function is to perform B-mode ultrasound scans. The system consists of 1) A console which supports 12 and 18MHz Posterior B scan probes and Anterior B- Scan, Ultrasound Bio-microscopy (UBM) probes with either 35 or 50MHz transducers. 2) A laptop which performs the image processing requirements of the system; provides the user interface for operating the device and viewing the resultant images. The laptop also provides data storage, export, archiving and networking for the device and includes the connection for footswitch.

V. Principle of Operation

In ophthalmic ultrasound imaging, a transducer emits a short acoustic pulse in response to a voltage transient generated by a pulser. Echoes are generated as the pulse propagates through eye tissue and encounters ophthalmic structures differing in acoustic impedance from their surroundings. When these echoes are received by the transducer they are converted back into voltages and amplified. The range of each echo is proportional to the time delay between pulse emission and echo return. Each pulse/echo provides information along a line of sight. By mechanically sweeping the transducer across an arc, information from a series of lines-of-sight is obtained. Converting the echo amplitude into pixel intensity allows a 2D cross-sectional B-Scan image to be displayed. This is the basis for B-Scan imaging.

VI. Indications for Use

Eye Prime is used for ophthalmic imaging when the following conditions are present or suspected:

- cataracts
- retinal detachments (a separation of the retina from the middle coat of the eyeball)
- orbital lesions
- tumours
- foreign bodies
- inflammation
- vascular irregularities.

VII. Comparison of Intended use and Technological Characteristics with Predicate Device

Model	**Eye Prime (proposed device)**	**Eye Cubed Version 4 (predicate device)**
510(K) number	N/A	K(103608)
Clinical application	Diagnostic ophthalmic ultrasound for use in Clinics/Hospitals by ophthalmologists, sonographers or trained echographers.	Diagnostic ophthalmic ultrasound for use in Clinics/Hospitals by ophthalmologists, sonographers or trained echographers.
Sterility	Non Sterile	Non Sterile
Patient population	Adult male and female	Adult male and female
Intended Use	Ophthalmic imaging when the following conditions are present or suspected: •cataracts •retinal detachments (a separation of the retina from the middle coat of the eyeball) •orbital lesions •tumours •foreign bodies •inflammation •vascular irregularities.	Ophthalmic imaging when the following conditions are present or suspected: •cataracts •retinal detachments (a separation of the retina from the middle coat of the eyeball) •orbital lesions •tumours •foreign bodies •inflammation •vascular irregularities.
Modes of Operation	B-Mode (Posterior and Anterior)	A-Mode (Biometry and Diagnostic) B-Mode (Posterior and Anterior)
Probe /Transducer type	Mechanical Sector (1 element)	Mechanical Sector (1 element)
	Annular Array (6 elements)	N/A
	N/A	Static Biometry A-Scan
	N/A	Static Diagnostic A-Scan
Transducer Frequency Range (MHz)	12-50	8-40
Image Acquisition Rate	10 FPS	12.5 - 50 FPS
Operating System	Windows 10	Windows XP
Internal Storage	512GB	160 GB
Image processing unit and User Interface	Laptop	A desktop computer with an external monitor is used to process image data and as the user interface
Electronic Medical Record (EMR) connectivity	DICOM(Digital Imaging and Communications in Medicine)	DICOM(Digital Imaging and Communications in Medicine)

Model	Eye Prime (proposed device)	Eye Cubed V4
Dimensions (inches)	3.4 x 6.9x8.9	6.5x15.3x16.9
Power requirements	100-240VAC, 50/60HZ, 50VA (console only)	100-240VAC, 50/60HZ,220VA
Acoustic output power MI < 0.23 Ispta.3 < 17 mW/cm	Track 1	Track 1
Compliance standards	* US Federal Performance * Standards 21 CFR 892.1560 and 21CFR 892.1570 for Class II Ultrasonic products -AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, -IEC 60601-1-2:2014 -IEC 60601 1-6:2010 + AMD1: 2013 -IEC 60601-2-37:2007 + AMD1:2015 -IEC 62366:2007+AMD1:2014 -ISO 10993-1 -NEMA UD2-2:2004	* US Federal Performance * Standards 21 CFR 892.1560 and 21CFR 892.1570 for Class II Ultrasonic products -IEC 60601-1 -IEC 60601-1-2 -IEC 60601-2-37 -ISO 10993-1 -NEMA UD2-2:2004

VIII. Summary of Non-Clinical Tests

The device has been evaluated for acoustic output, biocompatibility, as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform to the applicable medical device safety standards as below:

- **Safety and Product Specific testing:**
  - AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
  - IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

- IEC 60601 1-6:2010 + AMD1: 2013, Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
- IEC 60601-2-37:2007 + AMD1:2015, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- IEC 62366:2007+AMD1:2014, Medical devices – Application of usability engineering to medical devices
- ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological evaluation of Medical Devices- -Part 10: Tests for irritation and skin sensitization
- NEMA UD2-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

- **Biocompatibility Testing**

  The Eye Prime has two patient-contacting elements: the Posterior B-Scan Probes, the single use ClearScan transducer cover / Scleral Shells for the Anterior UBM probe transducers. In all cases, the patient-contacting materials were found to be biocompatible.

- **Software Verification and Validation Testing**

  Verification and Validation activities were designed and performed to demonstrate that the Eye Prime met pre-determined performance specifications.

- **Measurement accuracy**

  Eye Prime System has been verified and has been found to be equivalent in measurement accuracy to Eyecubed Version 4.

- **Risk Analysis Method Used**

  Ellex Medical Pty Ltd applied ISO-14971 to the design and development of the Eye Prime system. The conclusion from the risk analysis was the device was safe for its intended use and does not pose any unacceptable risks.

IX. Summary of Clinical Tests

Since the Eye Prime device uses the same technology and principles as the predicate device, clinical data is not required.

X. Substantial Equivalence Discussion

The Indications for Use for Eye Prime are exactly the same as predicate Eye Cubed Version 4 Diagnostic Ultrasound.

Technological characteristics of the Eye Prime are substantially equivalent with respect to the basic design and function of the predicate device. Both the subject and predicate device are based on the same ultrasound imaging and measurement principles. The major technological aspects they have in common are the following:

- Ophthalmic B-mode scanning for imaging and measurement.
- Ultrasound frequencies ranging from 8MHz to 50MHz.
- Windows PC or laptop for operator controls and display of measurements and images. Database for storage of measurements and images.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The systems have been designed in compliance with approved electrical and physical safety standards.

There are differences in the probes in the proposed device and there is neither the Biometry A-Scan nor the Diagnostic A-scan available for Eye Prime. However the modifications do not raise concerns for safety and effectiveness of the device based on the device safety and performance testing.

XI. Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the subject Eye Prime met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate device(s).