DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K190786

Device Name

Eye Prime

Indications for Use *(Describe)*

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

•Cataracts
•Retinal Detachment (separation of the retina from the middle coat of the eyeball)
•Orbital Lesions
•Tumors
•Foreign Bodies
•Inflammation
•Vascular Irregularities

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name	**Eye Prime System** Probes : Posterior B-Scan Probe (12 MHz), Posterior B-Scan Probe (18 MHz), Anterior B-Scan (UBM) Probe (35 or 50 MHz)
Intended Use	The Eye Prime is intended for ophthalmic imaging when the following conditions are present or suspected: •Cataracts •Retinal Detachment (separation of the retina from the middle coat of the eyeball) •Orbital Lesions •Tumors •Foreign Bodies •Inflammation •Vascular Irregularities

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	**Mode of Operation**							
	A	**B**	**M**	**PW Doppler**	**CW Doppler**	**Color Doppler**	**Power Doppler**	**Combined Modes**
Ophthalmic		N						
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric								
Small Organ								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N=new indication; P=previously cleared by FDA

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Probe	Ophthalmic Anterior Segment B-scan (UBM) probe
Intended Use	Imaging anterior segment of the eye. The probe may operate at a nominal frequency of 50 MHz or 35 MHz, depending on the transducer selected.

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	**Mode of Operation**							
	A	**B**	**M**	**PW Doppler**	**CW Doppler**	**Color Doppler**	**Power Doppler**	**Combined Modes**
Ophthalmic		N						
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric								
Small Organ								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N=new indication; P=previously cleared by FDA

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Probe	Ophthalmic 12 MHz Posterior Segment B-scan transducer
Intended Use	Imaging posterior segment of the eye

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	**Mode of Operation**							
	A	**B**	**M**	**PW Doppler**	**CW Doppler**	**Color Doppler**	**Power Doppler**	**Combined Modes**
Ophthalmic		N						
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric								
Small Organ								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N=new indication; P=previously cleared by FDA

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Probe	Ophthalmic 18 MHz Posterior Segment B-scan transducer
Intended Use	Imaging posterior segment of the eye

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	**Mode of Operation**							
	A	**B**	**M**	**PW Doppler**	**CW Doppler**	**Color Doppler**	**Power Doppler**	**Combined Modes**
Ophthalmic		N						
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric								
Small Organ								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N=new indication; P=previously cleared by FDA