

endoluxe

Endoscopic Visualization

Reimagined

Manufactured by



**ALL-IN-ONE PORTABLE & WIRELESS
ENDOSCOPIC VISUALIZATION SYSTEM**

Feedback to Clinicians & HIPAA Compliancy

- **Tele-Medicine:** Live streaming, patient data uploads, and device authentication to cloud application all compliant per HIPAA regulations.
- Cloud application hosted by AWS on HIPAA compliant server: **Feel safe knowing that your PHI data is secure in our HIPAA compliant AES-256 bit encrypted environment.**
- **Access from Any Device:** Access your data from any device. Provide secure shared links to your colleagues or patients to review their media.
- **OTA Updates:** Over the Air updates are pushed periodically and automatically to add/activate new features, user interfaces and apply critical updates
- **EMR / PACS Integration Capability:** Integrate images and video in existing EMR and PACS systems by storing dicom images.



endolux
Vision System

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Vision System



- The Endoluxe Vision System (eVS) is completely wireless with the capability to live stream procedure video and upload patient data to our HIPAA compliant cloud application.
- Current Application Use:

Urology (Cystoscopy, Ureteroscopy, TURP, TURBT, Eurolift, Reezum)

Gynecology (Hysteroscopy, Vaginoscopy)

Pulmonology (Bronchoscopy)

Orthopedics (Arthroscopy)

General Surgery (Laparoscopy, Sigmoidoscopy)

ENT (Otolaryngology)

Regulatory Compliances

- AVG Compliance with Endoluxe QMS
- FDA CFR 21Part 820 (GMP)
- MET Labs Certified: EN 60601
- FCC Certified Design
- ISO 13485 Compliant Manufacturing Facility

Medical Device Classification

Device: Camera, endoscopic, without audio

Product Code: FWL

Submission Type: 510(k) Exempt

Device Class: 1 (I)

GMP Exempt: No

Device: LED light source

Product Code: NTN

Submission Type: 510(k) Exempt

Device Class: 2 (II)

GMP Exempt: No

Safety Certification

MET Labs Listing E114977

Nationally Recognized Testing Laboratory (NRTL) by OSHA and FDA



Regulations

EN 60601 (Medical Equipment)

47 CFR CH. 1 – FCC Part 15 (RF)

ICES-003 Issue 6 (Interference)

EN 55032 (Radio Disturbance)

EN 55024 (Immunity)

ETSI EN 301-489 (Electromagnetic Compatibility)

UL 62368 (Safety Requirements)

Part	EN/UL 60601 Medical Electrical Equipment
1-2	General requirements for basic safety and essential performance - Collateral Standard; Electromagnetic disturbances - Requirements and tests
1-6	General requirements for basic safety and essential performance - Collateral standard; Usability
2-18	Particular requirements for the basic safety and essential performance of endoscopic equipment