

Packtion Potential

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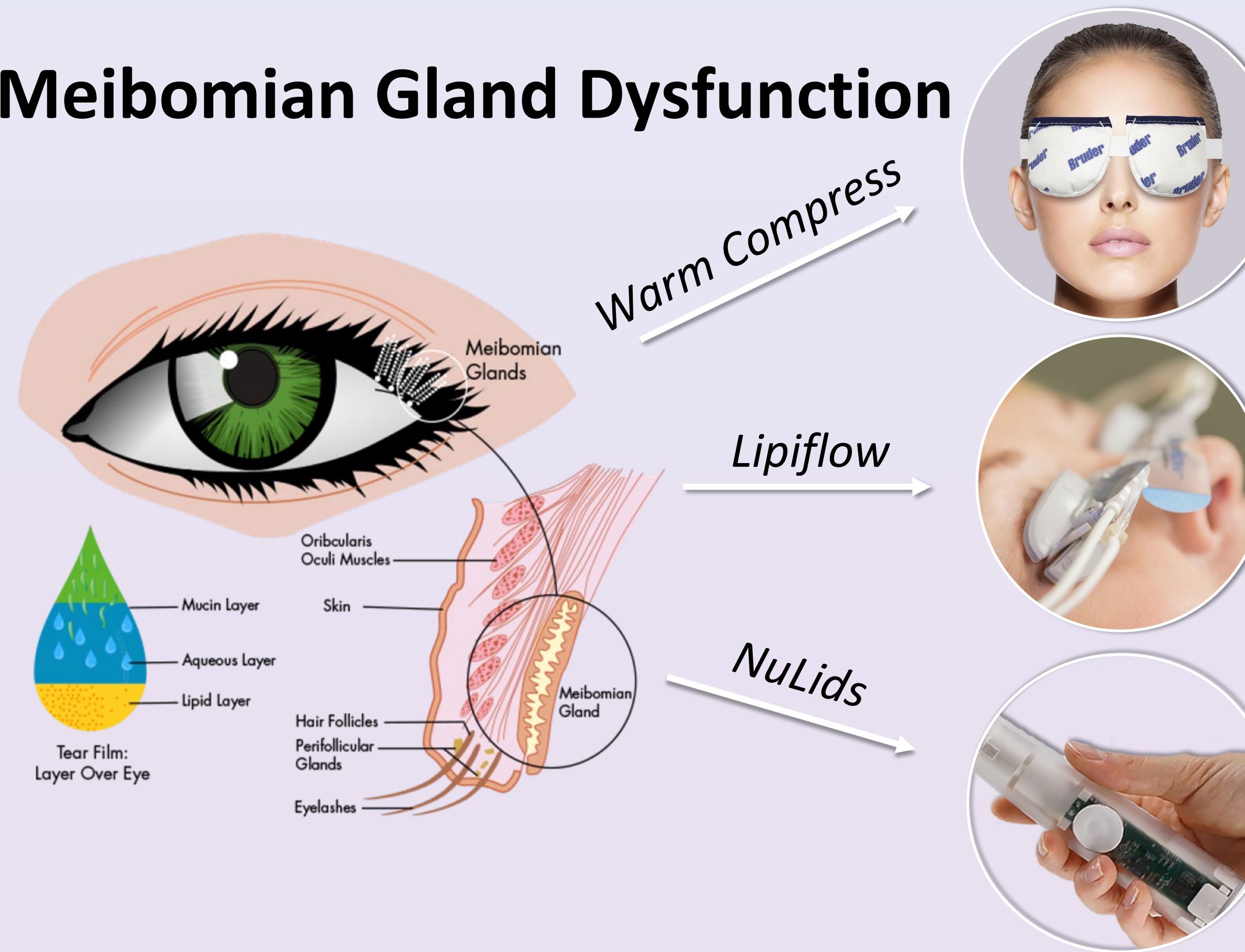
LumiSpecs

Joint Department of
BIOMEDICAL
ENGINEERING

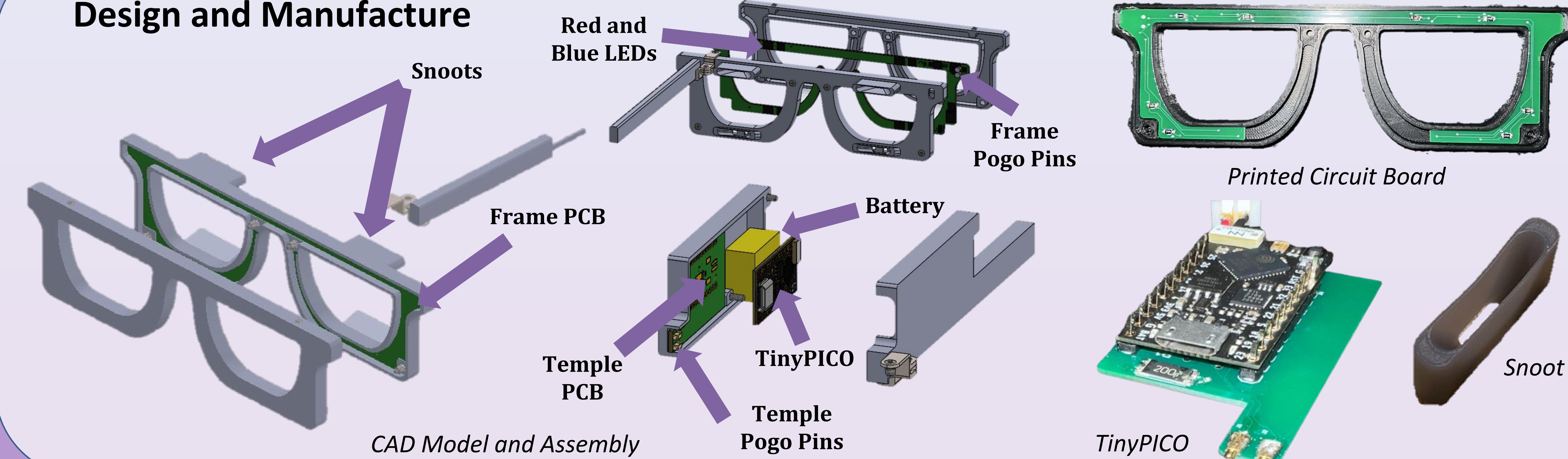
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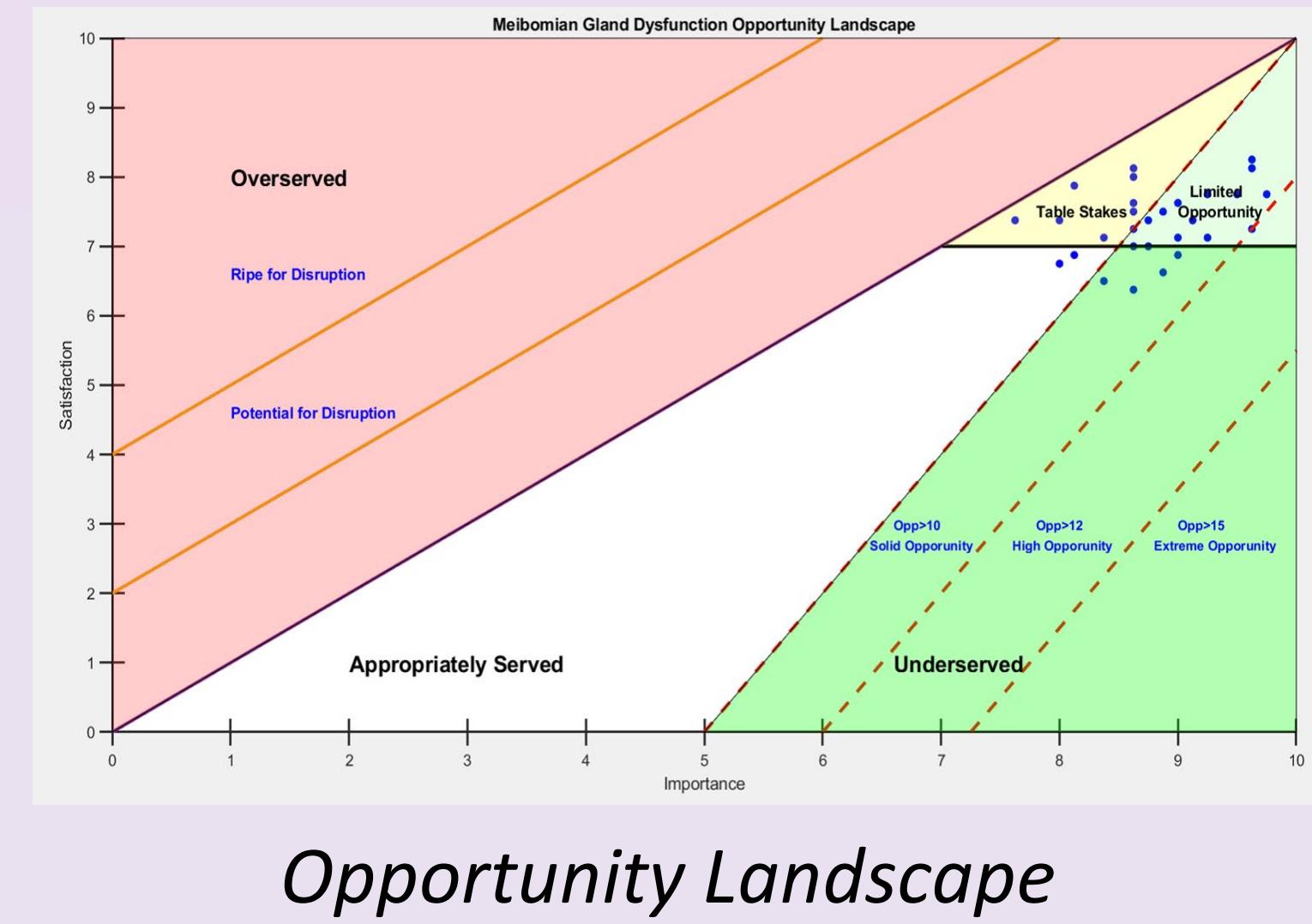
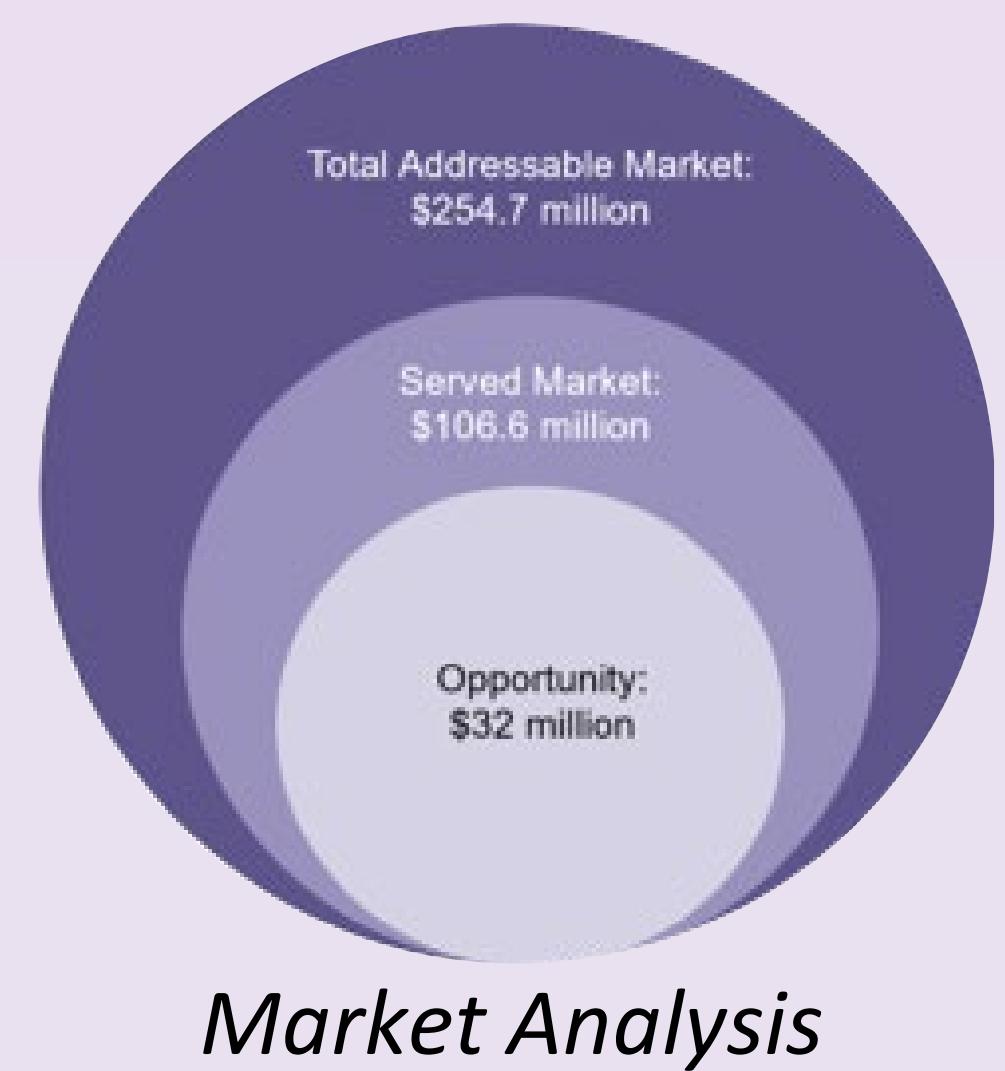
Meibomian Gland Dysfunction



Design and Manufacture



Market Analysis and Opportunity Landscape



Regulatory and Risk Management

- US Class 2 Device
- CE Class 1 Device
- Predicate Device: NuLids
- Relevant IEC Standards:
- Medical Electrical Equipment (Alarm Systems: 60601-1-8, EMC: 60601-1-1, At-Home: 60601-1-11)
- Home Light Therapy (60601-2-83)

Risk/Hazard	Mitigation
Snoots fall off so light is no longer directed	"Handle with Care" warning and directions
Snoots focus light in wrong direction	Physician Calibration and Drop Testing
Timer does not work, LEDs on for too long	Include manual instructions
Electric Shock during treatment or while plugging in device	Compliance with IEC 60601-1-1 Electrical Safety Testing
LumiSpecs do not stay on patient's face or do not fit	Add nose bridge and use adequate manufacturing tolerances

V&V Test Results

Test Number and Test	Pass/Fail
T00001 - Benchtop Testing	Pass
T00002 - Software Functionality Testing	Pass
T00003 - Hardware Functionality Testing	Pass
T00004 - Dynamic Impact Testing	Fail
T00005 - Photobiological Safety Testing	Pass



Benchtop Testing

Acknowledgements

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