ImPACT APPLICATIONS'

PRIMER ON WHAT IT MEANS
TO BE A CLASS II MEDICAL DEVICE

WHAT DOES IT MEAN TO BE A CLASS II MEDICAL DEVICE?

As Class II medical devices, our products:

- Must be **reviewed by the FDA** to obtain clearance upon first introduction and when any significant changes are made
- Have undergone **extensive testing** and in-depth internal review upon each release
- Are continuously **monitored** for compliance
- Have to **comply with all basic regulations** such as good manufacturing practices, truthful marketing claims, and reporting bad outcomes
- Have to meet additional requirements such as **clinical trial data**, software testing, and risk management.

WATCH VIDEO: [WHAT DOES IT MEAN TO BE A CLASS II MEDICAL DEVICE?]

HOW MEDICAL DEVICES ARE CLASSIFIED

FDA regulated medical devices are classified depending on their level of risk:

CLASS I
- low to moderate risk -

CLASS II
- moderate to high risk -

ImPACT
ImPACT Pediatric
ImPACT Quick Test

CLASS III
- high risk -