

## A MEDICAL DEVICE IS...

...an instrument, apparatus, implant, machine, tool, in vitro reagent, or similar article that is used to diagnose, prevent, mitigate, treat, or cure disease or other conditions, and, unlike a pharmaceutical or biologic, achieves its purpose by physical, structural, or mechanical action but not through chemical or metabolic action within or on the body.

The US Food and Drug Administration (FDA) reviews medical technology according to the risk to the patient, with higher risk products requiring more clinical evidence than lower risk products. FDA allows on the US market only those products that have met its requirements.

### FDA groups medical devices into *three* categories based on risk:

- 1 Class I products are low risk and do not require submission of data or information to FDA.
- 2 Class II products pose moderate risk and are cleared via 510(k).
- 3 Class III products are high risk, innovative products requiring a Premarket Approval Application.



## ADVAMED SECTORS



Ophthalmology



Orthopedics



In Vitro Diagnostics



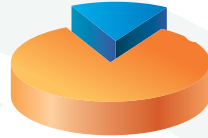
Wound Care

## ABOUT ADVAMED

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical technology association, representing about **400** manufacturers of medical devices, diagnostic products and health information systems.



Our members are leading the effort to transform health care through earlier disease detection, less invasive procedures and more effective treatments to help people live longer, healthier and more active lives. AdvaMed members range in size from the largest to the smallest medical technology innovators and companies.



About **80%** of our members are small and medium sized enterprises.

## OUR MISSION

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation. Initially established in **1974**, we provide members with the advocacy, information, education and tangible solutions necessary for success in a world of increasingly complex medical and business regulations.

Advanced Medical Technology Association | AdvaMed  
701 Pennsylvania Avenue, NW | Suite 800  
Washington, DC 20004-2654



[www.AdvaMed.org](http://www.AdvaMed.org)  
[facebook.com/AdvaMed](https://facebook.com/AdvaMed)  
[twitter.com/AdvaMedUpdate](https://twitter.com/AdvaMedUpdate)

# WHAT IS A MEDICAL DEVICE?



# EXAMPLES OF MEDICAL DEVICES



Diabetes Test Strips



Wheel Chair



MRI Machine



EKG Machine



Intraocular Lens



Pacemaker



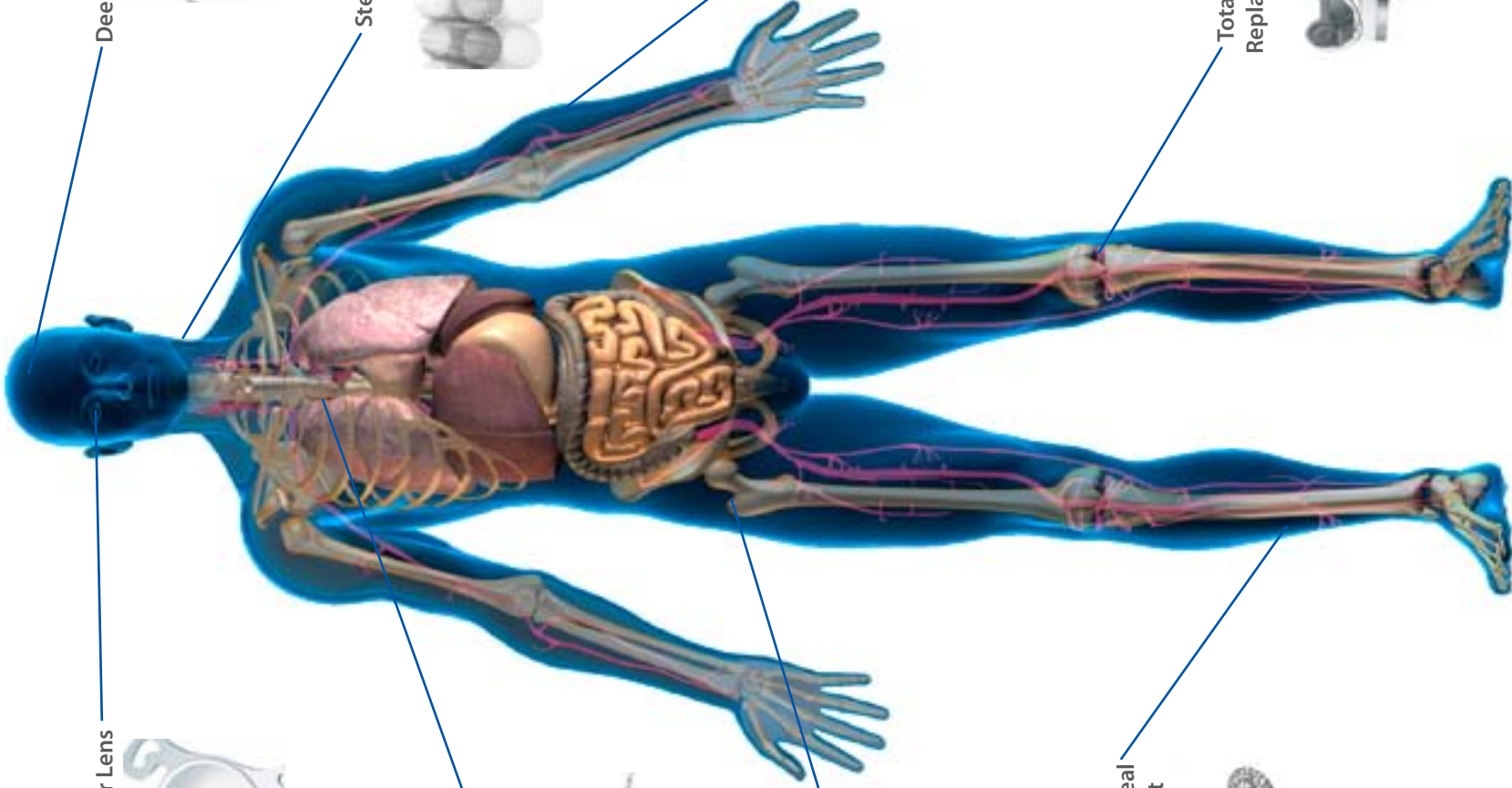
Deep Brain Stimulator



Stent



Hip Replacement



Total Elbow Replacement



Femoropopliteal Arterial Graft



Total Knee Replacement