

WHAT IS A MEDICAL DEVICE?

The differences and similarities between assistive technology, medical devices and consumer products.

FDA MEDICAL DEVICE DEFINITION

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

ASSISTIVE TECHNOLOGY DEVICE DEFINITION

The term 'assistive technology device' means any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities. (www.ataporg.org)

MEDICAL DEVICE QUIZ

Which products are medical devices?



HOME BED

Purchased from:
Local mattress store,
furniture store and
discount warehouses.

Intended use:
Comfort, reduce stress
and relieve pain.



CONTOURED PILLOW

Purchased from:
Local mattress store,
chiropractor or online.

Intended use:
More natural
alignment of your
neck and back,
Hypo-allergenic.



WALKER

Purchased from:
Home or durable
medical equipment
(DME) supply store
or online.

Intended use:
Aides in walking for
balance and control.



HOSPITAL BED

Purchased from:
Durable medical
equipment (DME)
supply store.

Intended use:
Often prescribed by a
healthcare provider.
Comfort, function,
pressure reduction
and safety.

Answers on reverse side.

HOME BED - Medical device: reduces back pressure and pressure points. **WALKER** - Medical device: aides in walking and balance. **CONTOURED PILLOW** - Medical device: Proper alignment of neck and back, hypo-allergenic. **HOSPITAL BED** - Medical device: Safety, comfort, specific medical purpose.

COMMON ASSUMPTIONS AND COMMON LINKS

COMMON ASSUMPTIONS:

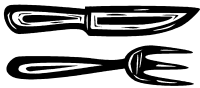
A prescription is needed to buy a medical device.

Consumer products are not medical devices when purchased “over-the-counter”.

INTENDED USE and CLAIMS = A MEDICAL DEVICE not assumptions.

COMMON LINKS:

ASSISTIVE TECHNOLOGY

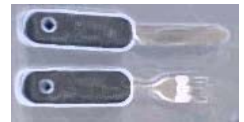


What modifications, intended use, or marketing claims can transform assistive technology like this everyday knife and fork into a medical device?

Modified to help people with Arthritis or weak grasp i.e. a larger rubber handle intended to affect a specific function.

Marketed as an Arthritis product sold directly to consumers.

MEDICAL DEVICE



IMPORTANT!!!

Some manufacturers are not aware that the “products” they manufacture are also “medical devices”.

Take a closer look at what the marketing really says and compare it to the actual product design.

Medical suppliers (DMEPOS), catalogs and internet marketing does not always match the manufacturers marketing.

Often products are used beyond or outside in the intended use.

Forecasting an outcome should be based on an appropriate assessment.

Identify and Understand Medical Device Use Errors

Questions excerpted from “*Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*”.

Have problems occurred with the use of other similar products? Why?

Does device use require physical, perceptual, or cognitive abilities that exceed those of the user?

How might the user’s abilities affect their use of the device?

Can safety and critical tasks be performed incorrectly and what effects would this have?