Medical Device Regulation in Israel

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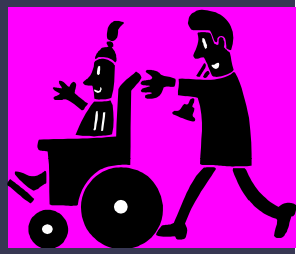
Health Technology

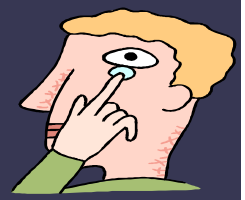
- Pharmaceutical
- Medical device 
- Biologics
- Medical procedure
- (cosmetics)

Israeli 'Medical Device' Definition

Any instrument, appliance or material intended to be used in human beings to achieve one of the following purposes:

- **Diagnosis, monitoring, prevention , alleviation, or treatment of a disease;**
- **Diagnosis, monitoring, alleviation of or compensation for an injury or a handicap;**
- **A replacement or accessory for an injured person;**
- **Examination, replacement, or modification of the anatomy of a physiological process;**
- **Control of conception.**





Exemption from all the above may apply to a medical device or a material, intended essentially to act in or on the human body through a medicinal agent.

Practical definition: A medical device is a device categorized as such by the FDA, European NB, etc'

Medical Device Registration

Who gives permits, licenses ?

- Centralized approach – USA – FDA – Center for Devices and Radiological Health (CDRH)

  (Safe Medical Device Act – 1976)

- De-centralized approached - EU – Certification (CE Mark) by Notified bodies licensed to issue permits by the competent authority (government)

  (Medical Device Directive MDD 93/42, Active Implantable Devices Directive - 1989, IVD 98/79, Medical Devices manufactured utilizing tissues of animal origin / incorporating animal tissues - 2003)

Medical Device Registration

How does one proves safety and efficacy of a medical device for registration purposes ?

Regulatory class: I, II, III (USA); I, II_a, II_b, III (EU)

USA – FDA:

- PMA – Pre-Marketing Approval – New Technology

OR:

- 510 (k) – substantially equivalence - “me too”

EU:

- Meet “Essential Requirements” according to a regulatory path you choose

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- Guidelines for the registration of medical devices and for the listing of implants **(Ministry of Health Director General Circular 1/95)**
- The guidelines have since been subject to certain amendments, and additions as follows: tissues, including corneas, for transplantation into human beings (March 1996); supplement for importation of whole blood and its products (February 1997); coronary stents (September 1997), etc.'
- Medical Device Law - 2012
- Centralized approach

Israel (Cont.) – Medical Device Registration Requirements

- Companies importing medical devices to Israel must request a pre marketing approval form the IMOH.
- Israel implements a medical devices registration process that corresponds to that of the USA FDA and EU ("two track system")
- The decision whether a medicinal product is a drug or a medical device as well as the classification of medical devices to regulatory classes are all based on FDA guidelines.
- Thus, the pre-market request should be accompanied by FDA's 510(k) or PMA approvals or CE Mark. In most cased, if such an approval does not exist, Canadian or Australian Therapeutic Goods can substitute the above mentioned certificates.

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