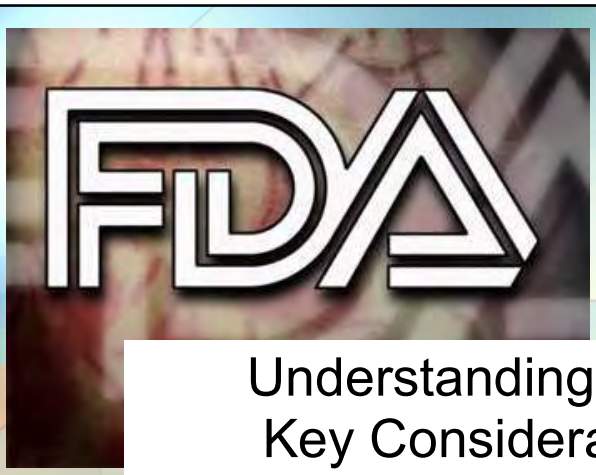


Understanding the FDA: Key Considerations for Regulatory Agencies

Donna M. Liewer

FCLB Executive Director

DISCLAIMER

This represents the Federation's best efforts to understand and interpret FDA requirements and is not evaluated or reviewed by FDA for content or accuracy

PS Donna Liewer is <u>not</u> an Attorney

CREDITS

Thanks to Mark Stafford, Esq.
Legal Counsel to the Kansas Board of Healing Arts
for guiding FCLB staff
through the FDA website and processes

What does FDA Recognition Mean for Regulatory Boards?

- The US Food & Drug Administration approves marketing **claims**, not **use**
  - **Medical devices (CDHR)**
  - **Dietary supplements (ONPLDS)**
  - **Also other areas not generally applicable to chiropractic regulatory boards**
- Approving USE of devices & supplements is a **regulatory board decision**
  - **But involves truthful marketing claims**

What does FDA Recognition Mean for Regulatory Boards?

- FDA does not actually inspect devices
- FDA reviews the application materials provided
  - **Should the device be allowed to be marketed for the purpose claimed?**

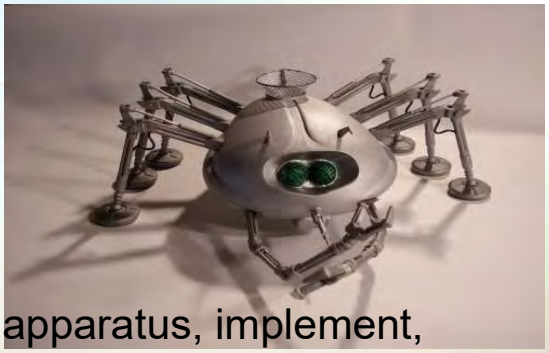
Medical Devices

Medical Devices

- Regulated by FDA's Center for Devices and Radiological Health (CDRH)
- Examples range from **simple** tongue depressors and bedpans to **complex** programmable pacemakers with micro-chip technology and laser surgical devices
- Subject to **premarketing** and **postmarketing** regulatory controls

Medical Devices Definition

According to Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act:



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

Medical Devices Definition

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, or
- 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

Medical Devices Definition

- 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."

aka

NOT food or drugs

Necropathic spectregraph is NOT FDA approved

Sec. 878.4810
Laser surgical instrument

Sec. 870.5900
Thermal regulating system

FDA Process for Medical Devices

- Is it a Medical Device? (Definition)
- Which of 3 Classifications?
  - **Depends on intended use & indications for use**
  - **Also depends on predicate devices**
    - **"Substantially equivalent"**
- May need clinical performance data
- Comply with other requirements
  - **General Controls**
  - **Special Controls**
  - **Premarket Clearance / Postmarket surveillance**

Three Classification Levels

- Classification determines whether they require
  - **Premarket notification - 510(k)**
  - **Premarket approval – PMA**
  - **Or may be Exempt**
    - **IDE = Investigational Device Exemption during clinical trials**

Classifications

- **Class I (low risk)**
  - usually exempt (74%) from premarket notification requirements
  - **General controls** are sufficient
- **Class II = sometimes exempt**
  - General controls alone are insufficient to assure safety and effectiveness
  - Existing methods are available to provide such assurances – called **"special controls"**
- **Class III = not exempt unless before 1976 (high risk)**
  - Supports or sustains human life, or
  - Are of substantial importance in preventing impairment of human health, or
  - Presents a potential, unreasonable risk of illness or injury

General Controls for Devices

- Establishment Registration with FDA
  - **Within 30 days of commercial distribution**
  - **Location, owner/operator**
- Listing with FDA
  - **Within 30 days of commercial distribution**
  - **Includes manufacturers, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers**
- Labeling
- Good manufacturing process

2008 - 2009

CERTIFICATE OF REGISTRATION

This certifies that:

Roy Chocolatier
27 rue de Longchamp
Paris F-75116
France

is registered with the U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as currently effective on the date hereof by FDA Registrar Corp.

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Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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info@fdaregistrar.com • www.fdaregistrar.com

Russell K. Stattman
Executive Director
FDA Registrar Corp.
Dated: February 5, 2008

Example of Establishment Registration

This is NOT FDA approval

Special Controls for Devices

- May include:
  - **Special labeling requirements**
    - **Example: Limitation of sales by prescription only**
    - **501(k) letter will say "prescription only"**
    - **Technical requirement is that device is labeled with the legend:** **WARNING: Federal law prohibits dispensing without prescription…**
  - **Mandatory performance standards**
  - **Postmarket surveillance**

Premarket Clearance

- Two options:
  - **510(k) letter**
  - **Premarket Approval (PMA)**
- Boards will find this info in two different FDA databases

Postmarket Controls

- Quality System (QS)
  aka Good Manufacturing Practices
  - **Design, packaging, labeling and manufacturing of a medical device**
- Medical Device Reporting (MDR)
  - **Adverse event reporting program**
  - **On-line database has 600,000 reports**
    - **1984 – 1996**
    - **Discontinued, replaced by MAUDE**
- MAUDE (Manufacturer and User Facility Device Experience) – searchable database

Types of devices

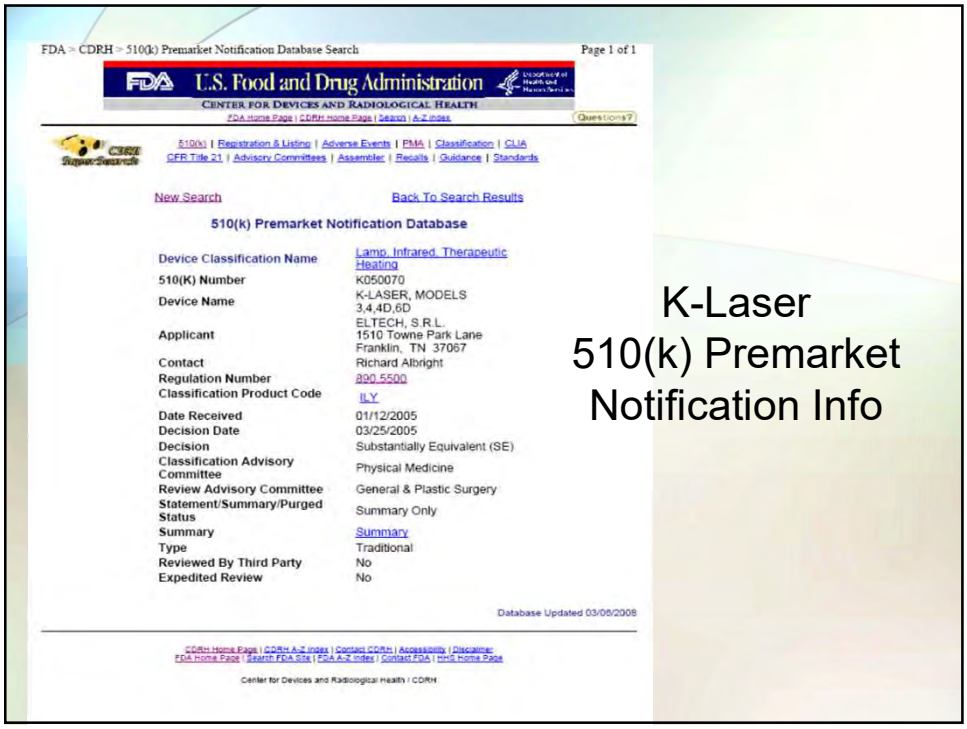
- **1700** types of devices in 16 “panels”
- Chiropractic boards will most often see devices in
  - **Panel 890 = Physical Medicine**

What is a 510(k) letter?

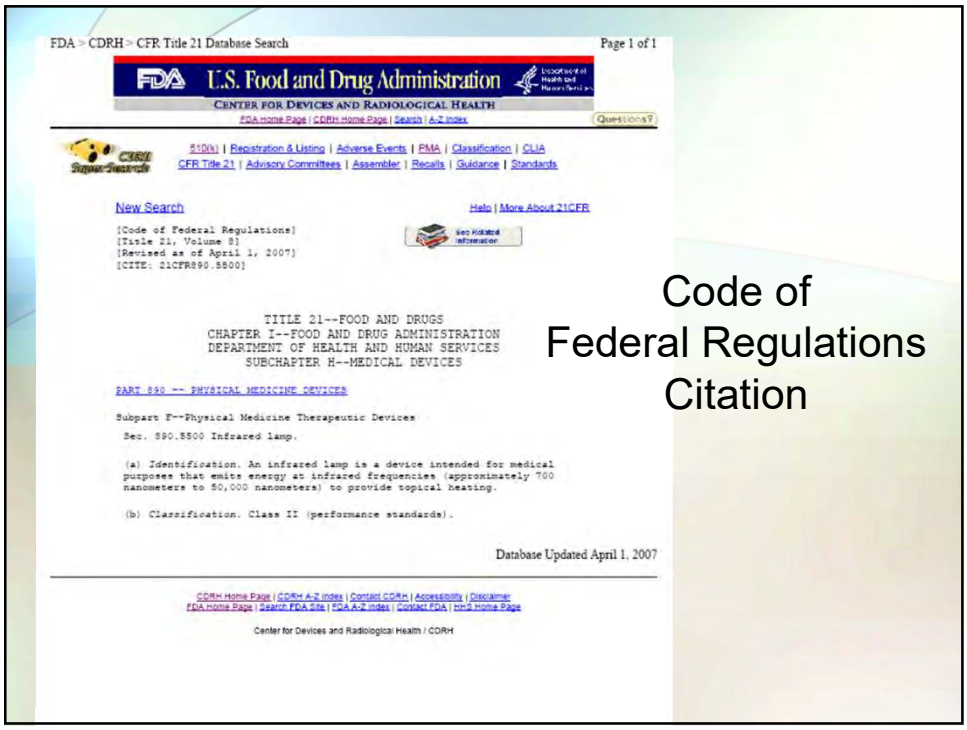
- Specifies important info for boards!
  - **Registrant / Contact Info**
  - **Exact name of device**
  - **Regulation # and Name**
    - **e.g., "power traction equipment**
  - **Class (I, II or III)**

510(k) Info for Boards (continued)

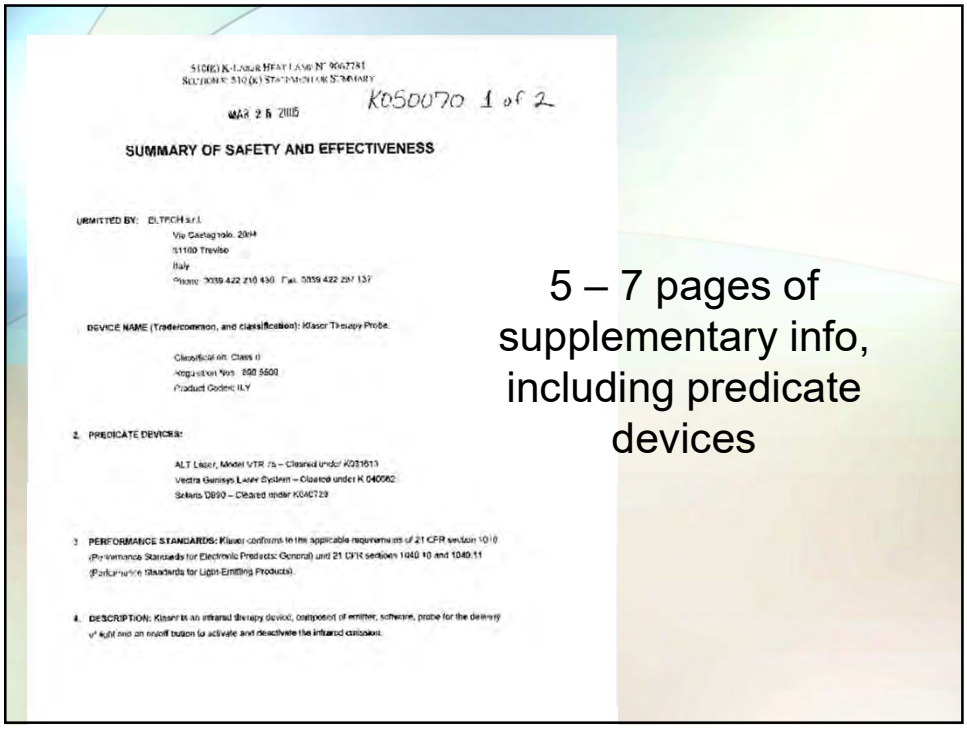
- **Reference # in Code of Fed Regulations**
- **Date of approval to market device**
- **Intended use, indications for use**
- **Prescription vs. OTC**
- **Any predicate devices**
- **Summary of safety & effectiveness**



K-Laser
510(k) Premarket
Notification Info



Code of
Federal Regulations
Citation



SUMMARY OF SAFETY AND EFFECTIVENESS

K050070 1 of 2

SUBMITTED BY: ELTECH S.r.l.
Via Castagnole, 20/4
31100 Treviso
Italy
Phone: 0039 422 210 430 Fax: 0039 422 297 137

DEVICE NAME (Tradecommon, and classification): Klaser Therapy Probe.

Classification: Class II
Regulation No: 890.5500
Product Codes: ILY

2. PREDICATE DEVICES:

ALT Laser, Model VTR 7s – Cleared under K031613
Vectra Genisys Laser System – Cleared under K 040662
Sellera D890 – Cleared under K040729

3. PERFORMANCE STANDARDS: Klaser confirms to the applicable requirements of 21 CFR section 1010 (Performance Standards for Electronic Products: General) and 21 CFR sections 1040.10 and 1040.11 (Performance Standards for Light-Emitting Products).

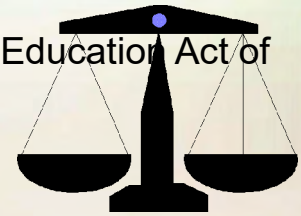
4. DESCRIPTION: Klaser is an infrared therapy device, composed of emitter, software, probe for the delivery of light and an on/off button to activate and deactivate the infrared emission.

5 – 7 pages of supplementary info, including predicate devices

Dietary Supplements

Dietary Supplements

- Regulated by FDA's Office of Nutritional Products, Labeling, and Dietary Supplements **(ONPLDS)**
- Center for Food Safety and Applied Nutrition **(CFSAN)**
- Dietary Supplement Health and Education Act of 1994 **(DSHEA)**
  - **Manufacturer is responsible for safety before marketed**
  - **FDA takes action against unsafe products after they reach the market**



Dietary Supplements

- Generally, manufacturers do <u>not</u> need to **register** products with FDA nor get FDA **approval** before producing or selling
- Manufacturers must ensure product label information is **truthful** and **not misleading**
- **<u>Not</u>** required to report **injuries or illnesses** that may be related to products

Dietary Supplements

- FDA monitors **safety**
  - **Voluntary dietary supplement adverse event reporting**
  - **Product information**
    - **Labeling**
    - **Claims**
    - **Package inserts & literature**
- Federal Trade Commission regulates dietary supplement **advertising**

FDA Oversight – via 3 Acts

- 1990 Nutrition Labeling and Education Act (NLEA)
  - **FDA issues regulations after careful review of scientific evidence submitted in health claim petitions**
- 1997 Food and Drug Administration Modernization Act (FDAMA)
  - **Health claims based on authoritative statement of scientific body of the U.S. government or National Academy of Sciences**
  - **Such claims used after submitting notification to FDA**
- 2003 FDA *Consumer Health Information for Better Nutrition Initiative*
  - **Health claims where quality and strength of scientific evidence falls below that required for FDA to issue authorizing regulation**

What is a Dietary Supplement?

- Vitamin
- Mineral
- Herb or other botanical
- Amino acid
- Dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or
- Concentrate, metabolite, constituent or extract

Dietary Supplements

- There is **no list** of FDA approved dietary supplements for boards to check
- Boards should understand the **three types of claims** that manufacturers can make legally
  - **Health**
  - **Nutrient Content**
  - **Structure / Function**

What is a Health Claim?

- Describes a **relationship** between
  - dietary supplement **ingredient**, and
  - **reducing risk** of a disease or health-related condition

What is a Nutrient Content Claim?

- **Describes the level** of a nutrient or dietary substance in the product
  - Such as *free*, *high*, and *low*, or
- **Compares the level** of a nutrient in a food to that of another food
  - Such as *more*, *reduced*, and *lite*

What is a Structure / Function Claim?

- Describes the **role** of a nutrient or dietary ingredient intended to affect normal structure or function in humans
  - **"calcium builds strong bones"**
- OR Characterizes the **means by which it acts** to maintain such structure or function
  - **"fiber maintains bowel regularity" or "antioxidants maintain cell integrity"**
- OR describes **general well-being** from consumption of a nutrient or dietary ingredient
- OR describes a benefit related to a nutrient **deficiency** disease (like vitamin C and scurvy)
  - **Provided the statement also tells how widespread such a disease is in USA**

Structure / Function Claims

- Must be accurate and truthful, not misleading
- Claims are not pre-approved by FDA
- Must include "disclaimer" that FDA has not evaluated the claim
- Disclaimer must also state that it is not intended to "diagnose, treat, cure or prevent any disease"
  - because only a **drug** can **legally** make such a claim
- Must notify FDA within 30 days of marketing if making structure / function claims

CHK Nutrition Page 1 of 1

CHK Home Page

CHK Nutrition
8721 Falcon St.
Duluth, MN 55808
Phone: 877-538-8388

Clinical Health and Knowledge through Nutrition

Committed To Sponsoring Formal Medical Education

DISCLAIMER: The products sold by CHK are nutritional supplements intended to provide support for neurotransmitters. These statements have not been evaluated by the Food and Drug Administration (FDA). These products are not intended t diagnose, treat, oure, or prevent any disease.

Off-Label Uses

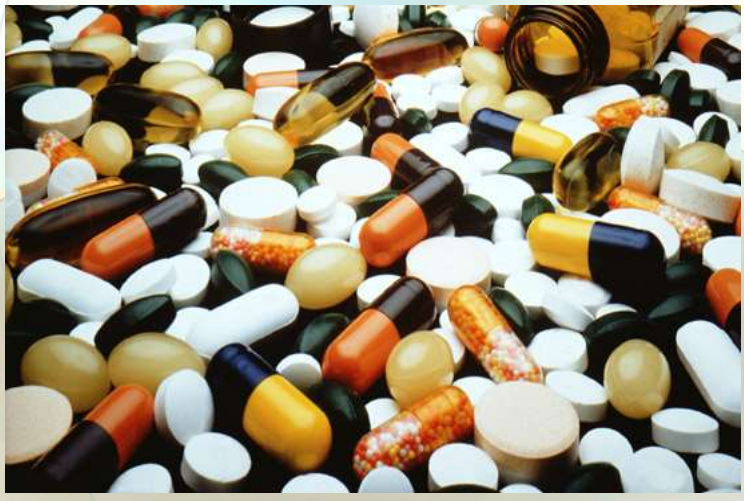
Off-Label Uses

- **Botox example**
  - 1989: FDA approved for facial neurological movement disorders
  - 2002: FDA approved to combat wrinkles and excessive underarm sweating
  - Currently, FDA approved for **both** cosmetic and therapeutic uses
- Until 2002, it wasn't illegal from FDA to **use** Botox for wrinkles but it was prohibited to **advertise** it for wrinkles

Off-Label Uses

- Decisions about **Off Label USES** are up to licensing boards
- To support off-label use: boards should look for a substantial body of
  - **Evidence; or**
  - **Tradition; or**
  - **Authority**

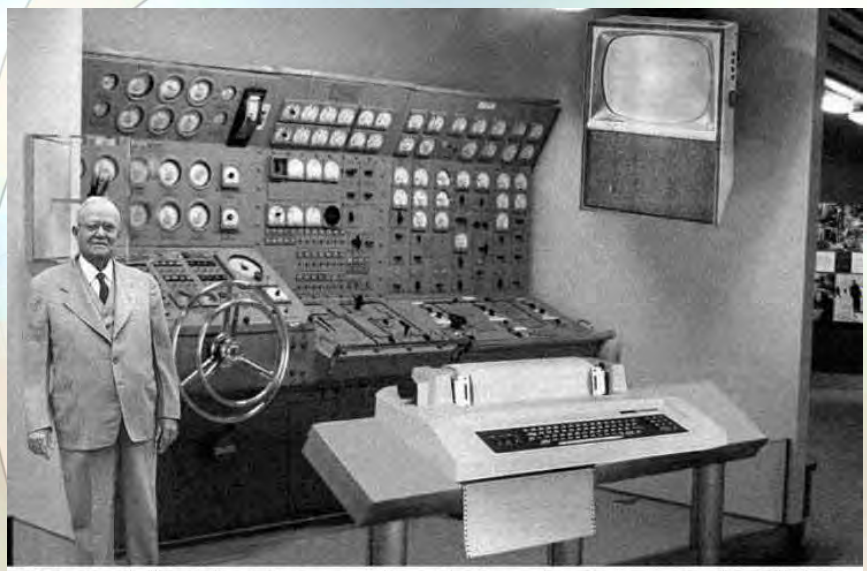
Over the Counter Drugs



Over the Counter Drugs: FDA definition

- Drugs that do NOT require a doctor's prescription
- Bought off-the-shelf in stores
- Regulated by FDA through OTC Drug monographs
- “Recipe book" covering acceptable ingredients, doses, formulations, and labeling
- Products conforming to monographs may be marketed without further FDA clearance
- Non-conforming products must undergo separate review and approval through the "New Drug Approval System"

FDA Resources for Regulatory Boards



Scientists from the RAND Corporation have created this model to illustrate how a "home computer" could look like in the year 2004. However the needed technology will not be economically feasible for the average home. Also the scientists readily admit that the computer will require not yet invented technology to actually work, but 30 years from now scientific progress is expected to solve these problems. With teletype interface and the Fortran language, the computer will be easy to use.

Board Resources

www.fda.gov

- **Click on Medical Devices**
  - Device Advice
  - Under Resources: **CDRH Databases**
    - 510(k) notification letters
    - PMA – "private license for Class III"
    - MAUDE (Manufacturer and User Facility Device Experience) – searchable adverse reports

Board Resources

- **Current drug list:**
  - **http://fda.gov/cder/ndc/database**
- **MEDWATCH**
  - **"Concise, timely information about the drugs and devices you use, prescribe, or dispense every day, directly from the U.S. Food and Drug Administration"**

  http://www.fda.gov/medwatch
  - **Click on "join the e-list" - FREE**

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