



Regulatory Strategy

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Agenda

- Foundations
- Medical Device Definition
- Is this a medical device?
- Device Classification
- Clinical Trials and IDEs
- Regulatory Hacks/Vignettes
- Engineering Standards & QMS
- Navigating FDA Resources

Note: This presentation is slightly more oriented towards devices/software and US strategy.





Why learn about this at all?

Medical technologies (devices, drugs, biologics, software) require approval before selling to the public.

A crucial milestone. Top concern for 80% of medtech CEOs. Completely different from reimbursement.

Regulatory consultants exist. They are expensive. You need to figure out strategy early (when poor).

Consultants also charge based on how much you know. Doing your own legwork will save you hundreds of thousands, if not millions of dollars.

Foundations

Two main systems are FDA (US) and CE mark (EU).

Other countries rely on a derivative system.

Australia relies on CE mark (90% of TGA-approved devices utilise CE mark).

CE mark was easier than FDA, but is undergoing a massive redesign (likely will be more difficult).

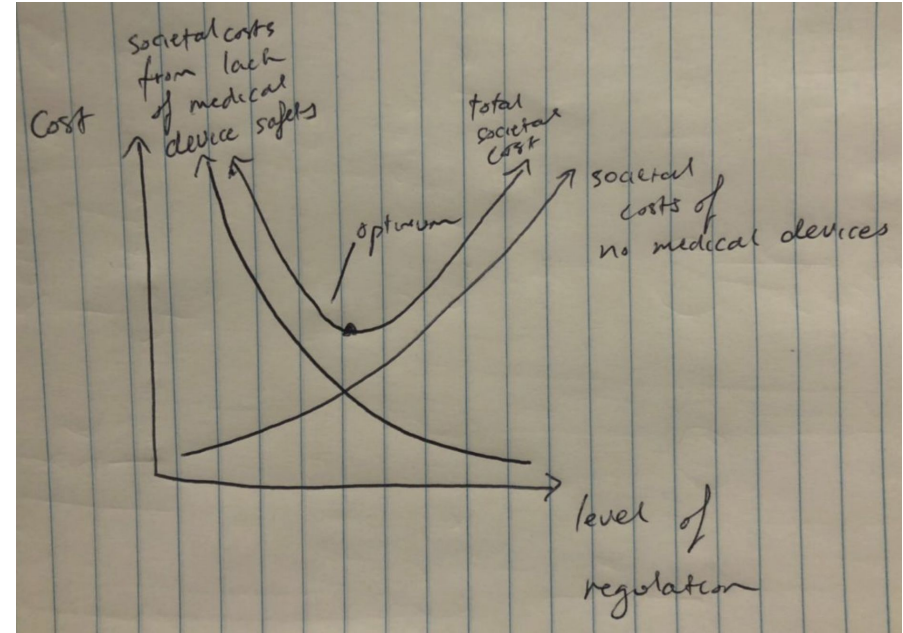


Regulatory Paradigm

Protection vs Patient Autonomy

Product Availability vs Safety/Effectiveness

Lower tolerance for smaller market sizes



FDA Mandate

Assesses **safety** and **effectiveness** (not allowed to consider cost)

- **Safety:** Reasonable assurance that device is safe based on valid scientific evidence that probable benefits for its intended uses outweigh probable risks.
- **Effectiveness:** Reasonable assurance that device is effective based on valid scientific evidence that in a significant portion of the target population the use of the device for its intended uses will provide clinically significant results



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Valid Scientific Evidence: Animal tests, bench tests, biocompatibility tests, similar device comparisons, clinical trials (controlled, non-controlled, case histories, human experience)



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Intended uses/target population are crucial to think about (more later).

- Broad vs Narrow
- Staged Strategy?
- Classification (e.g. similarity, ophthalmic scalpel)



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Clinically Significant Results

Has to show an effect (e.g. against placebo)

Main difference against CE mark



CE Mark Mandate

Assesses **safety** and **performance**

- **Safety:** Similar to FDA
- **Performance:** Ability of device to achieve its intended purpose as stated by the manufacturer

Historically:

- CE mark did not provide significant guidance and definitions were vague
- Obtaining CE mark was **a lot** easier
- After some disasters, CE mark are cleaning house. Majority of devices need to be recertified. Most believe CE mark have gone too far, so Europe is a less attractive market for now.



FDA Medical Device Definition



“Device intended for use in cure, mitigation, treatment, detection, prevention, diagnosis of diseases or intended to affect the structure or function of the body, which does not achieve its primary intended purpose through chemical action and is not dependent on being metabolised”

Covers most things (incl. software) except for drugs, biological products and some software as per 21st Century Cures Act (admin support, encouraging healthy lifestyles, EMRs, data transfer/storage/display)

If you have any medical claim, it is definitely a medical device. If you don't, it might also be.

Combination Device: Comprises of two or more regulated components (device, drug, biologic).

CE Mark Medical Device Definition



“An instrument, whether used alone or in combination (including software), to be used for human beings for diagnosis, prevention, monitoring, treatment, alleviation, compensation of any disease/injury, investigation/replacement/modification of anatomy or physiological process, control of conception which does not achieve principal intended action by pharmacological/immunological/metabolic means (but may be assisted in its function by such means)”

Similar definition to FDA and almost never differs



FDA Advice for CDSS

CDSS are NOT medical devices if they meet ALL of the following four criteria:

1. Software does NOT acquire, process or analyse any medical images, signals or patterns.
2. Software function displays, analyses or prints medical information normally communicated between healthcare professionals.
3. Software provides recommendations to a provider rather than provide a specific output or directive.
4. Software function provides the basis of the recommendations so that the provider does not rely primarily on any recommendations to make a decision.

Is this a medical device?

Blood Pressure Device
Used Cardiac Catheter
Water Filtration System
Drug Eluting Stent
Device which pushes medications to the back of your nasopharynx
Condoms
Mental Health Apps
Contact Lens
Decorative Contact Lens (just changes eye colour)
Leeches

“Device intended for use in cure, mitigation, treatment, detection, prevention, diagnosis of diseases or intended to affect the structure or function of the body, which does not achieve its primary intended purpose through chemical action and is not dependent on being metabolised”





Is this a medical device?

Blood Pressure Device - Yes, detects hyper/hypotension

Used Cardiac Catheter - Yes, if cleaned and resold (legal in US)

Water Filtration System - No, but yes if used in dialysis machines

Drug Eluting Stent - Yes, combination device

Device which pushes medications to the back of your nasopharynx - Yes, combination device

Condoms - Yes, prevents STDs

Mental Health Apps - Potentially and depends on claims

Contact Lens - Yes, treats myopia/hyperopia

Decorative Contact Lens (just changes eye colour) - Yes, affects the body structure

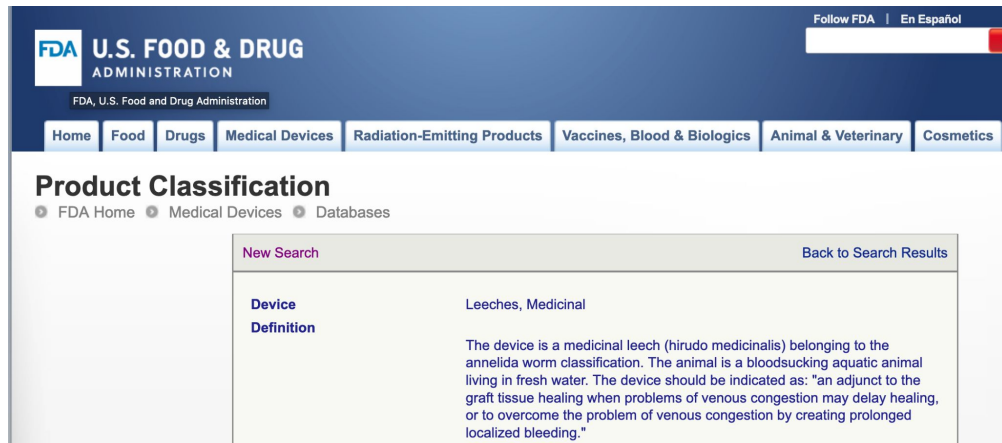
Leeches - Yes, combination device (mechanical suction of blood and anaesthetic injection)

“Device intended for use in cure, mitigation, treatment, detection, prevention, diagnosis of diseases or intended to affect the structure or function of the body, which does not achieve its primary intended purpose through chemical action and is not dependent on being metabolised”

What if I'm unsure?

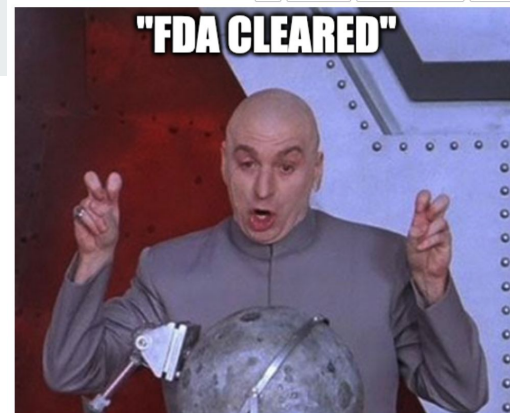
- Search FDA website (extremely useful resource)
- Search similar devices
- Speak to a regulatory consultant
- Speak to the FDA

Don't pull a Theranos and try to escape this.



The screenshot shows the FDA website's navigation bar with links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, and Cosmetics. Below the navigation bar is the "Product Classification" section, which includes a breadcrumb trail: FDA Home > Medical Devices > Databases. A search bar is present with a "New Search" button and a "Back to Search Results" link. The search results display the following information:

Device	Definition
Leeches, Medicinal	The device is a medicinal leech (<i>hirudo medicinalis</i>) belonging to the annelida worm classification. The animal is a bloodsucking aquatic animal living in fresh water. The device should be indicated as: "an adjunct to the graft tissue healing when problems of venous congestion may delay healing, or to overcome the problem of venous congestion by creating prolonged localized bleeding."



FDA Device Classification

Risk-based classification. Any medical claims = at least Class I.

- **Class I - Low Risk (55%):** Requires device registration (minority require 510k)
- **Class II - Moderate Risk (44%):** Requires a pre-market notification (510k)
- **Class III - High Risk (1%):** Requires a pre-market approval (PMA) (minority can 510k)

Determine class by referring to devices which have been approved before. If completely new, some flexibility.

Terminology matters.

- "FDA Registered" = Class I
- "FDA Cleared" = Class II, Standard 510k
- "FDA Granted" = Class II, De Novo 510k
- "FDA Approved" = Class III, PMA



Standard 510k (Clearance)

Requires proof of substantial equivalence to predicate devices in safety and effectiveness.

- **Predicate Device**
 - Previous 510k device or device on market before 1976.
 - Must have same intended use (and product code)
 - Doesn't cover PMA devices. If you get a PMA, everyone who follows you must get a PMA.
- **Split Predicates**
 - Can mix and match from **predicates from the same intended use** (e.g. circuit from device A, housing from device B). You claim one predicate as the “primary predicate”.
 - More predicates / newer components = greater burden of proof (but more novel)
- 90% of companies require bench testing, 10% require actual clinical testing

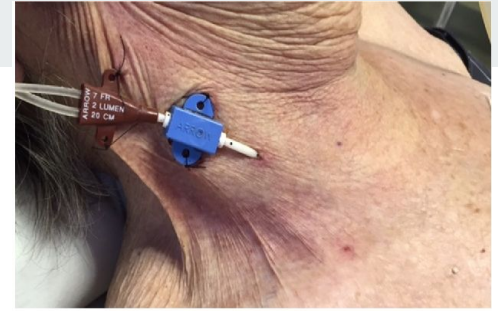
Great pathway for incremental improvements, slight tech transfers or “me-too”s



Substantial Equivalence

(same intended use as primary predicate) AND ((same technological characteristics) OR (different technological characteristics with appropriate evidence of safety/effectiveness))

- **Intended Use:** What the general purpose of the device is
- **Indications:** What exact disease you're using it for



Real-World Examples

Product	Intended Use	Indications
Vascular Catheters	Provide access to vasculature for diagnosis/treatment	Stroke Coronary Artery Disease Peripheral Vascular Disease
Fixation Plate	Support structure for diaphyseal/epiphyseal fractures	Middle Bone Fractures Long Bone Fractures
Cognitive Behavioural Therapy App	Improves medication adherence	Depression Anxiety Opioid Use Disorder

Substantial Equivalence

Elements of Comparison	Subject device	Predicate Device	Secondary Predicate Device
510(k) Number	K163393	K102598	K130723
Device Name and Model	Powered Muscle Stimulator and Transcutaneous electrical nerve stimulator for pain relief HD-5N	JQ-5C	FDES106(ED406) Mini TENS&EMS Device
Manufacturer	Hi-Dow Electron Technology(Hefei) Inc., Ltd.	Hefei Jianqiao Sci-tech Development Co., Ltd	Famidoc Technology Co., Ltd
Intended Use & Indications for Use	TENS To be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. EMS: Intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	To be used for the temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	For program N, B and H of TENS mode To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household work activities. For program E1 and E2 of EMS mode Used to stimulate healthy muscles in order to improve and facilitate muscle performance.
Basic Unit Characteristics			
Device Power Source(s)	DC 3.7V Lithium Battery	DC 3.7 V Lithium Battery	Battery powered, d.c. 3.0V, 2 X AAA batteries
-Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	Type BF Applied Part

Patient Leakage Current	NC	DC:<10µA AC:<100 µA	DC:<10µA AC: <100 µA	0.9µA
	SFC	DC:<50µA AC:<500 µA	DC:<50µA AC: <500 µA	0.8µA
Number of Output Channels	2		2	1
Number of Output Modes	4		6	5
Synchronous or Alternating?	2 Channel Asynchronous		2 Channel Synchronous	Alternating
Method of Channel Isolation	Two separate devices, and use independent power supply system.		Parallel	By Electrical Circuit and Software
Regulated Current or Regulated Voltage?	Regulated Voltage		Regulated Voltage	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes		Yes	Yes
Automatic Overload Trip?	No		No	Yes
Automatic No-Load Trip?	No		No	Yes
Automatic Shut Off	Yes		Yes	Yes
User Override Control?	Yes		Yes	Yes
Indicator Display	On/Off Status?	Yes	Yes	Yes
	Low Battery?	Yes	Yes	Yes
	Voltage/Current Level?	No	No	No
Timer Range	45mins		10 – 60mins	30 mins
Compliance with 21 CFR 898?	Yes		Yes	Yes
Weight (lbs., oz.)	Remote: 2.2 oz.		1.5 oz.	.093 oz.
	Receiver: 0.85oz.			
Dimensions (in.) [W x H x D]	Remote: 4.25"(W) x 2.1" (H) x 0.6" (D)		3.15"(W) x 1.65" (H) x 0.55"(D)	2.5"x1.77"x0.36"
	Receiver-Φ2.25" (Diameter) x 0.47"(D)			



De Novo 510k (Grant)

- Pathway created for low-moderate risk devices without a predicate
- Previously, any devices without predicate needed a PMA
- Created to spur creation of novel devices
- Longer (~1y) than standard 510k (~6mo), but much faster/cheaper than PMA (~1y for approval + much more rigorous trial)
- People used to be scared of it, but often viewed favourably (IP/market benefit)



Other 510ks

Special 510k

- Rapid pathway for modifications of already approved devices.
- Includes software updates if it “substantially impacts performances”
- If you choose not to file your software update, you must keep notes detailing the reasons why in a “letter to file”. The FDA is allowed to ask for these at any time.

Abbreviated 510k

- Rapid pathway for when an FDA guidance document has been provided for specific topic, special controls have been established or the FDA has recognised a relevant consensus standard.
- Highly recommended when possible. Requires regular tracking of FDA guidances. Sometimes related to special scenarios (e.g. COVID-19 pandemic).



CE Mark Device

Classification and process is similar to the FDA.

- **Class I:** Devices that do not enter into contact or interact with the human body.
- **Class IIa:** Non-active invasive or non-invasive devices for short-term use.
- **Class IIb:** Non-active devices that are partially or totally implantable within the human body and that are intended for long-term use (e.g. contact lens).
- **Class III:** Devices that affect the functioning of vital organs or life support systems, devices that enter into contact with the vasculature or the central nervous system.

Class I = self-certify/register. Class II-III = audit by Notified Body.

Notified Bodies are private organisations accredited to check by EU Governments.



Differences to FDA

- **Notified Bodies:** Decentralisation of approval, led to manufacturers seeking the “easiest” NBs, system has been restricted to highest quality NBs - will lead to massive backlog because most devices need to be re-certified
- No De Novo 510k Equivalent
- No Predicate System (however, clinical data from similar devices can be used)
- CE Mark doesn't publish any guidance, which makes things very difficult, particularly for novel devices
- Implant definition (>30d in US, >21d in Europe)



Current CE Mark Changes



Medical Device Directive (MDD) -> Medical Device Regulations (MDR)

- Increased clinical evidence requirements
- Increased post-market surveillance requirements
- Most medical AI will be reclassified to a higher class (minimum Class IIa for any risk score/diagnosis software)
- Designated “person responsible for regulatory compliance”
- All devices must be recertified under MDR
- Stricter requirements for Notified Bodies
- Swanky new logo, deadline is May 2024

Expected Impact

- Significant uncertainty until 2024 (with delays in regulatory approval)
- Improved device quality and adverse event detection
- Higher costs to get to market and therefore higher prices
- Predicted consolidation/oligopoly in European markets
- Even fewer devices in Australia (because we follow CE mark)



Qs + Biobreak



Clinical Trials

- Intimately tied with regulatory strategy
- Primary milestones for funding and timeline
- Probably 50-80% of your company's expenses (\$2K-500K per subject)

First in Human -> Early Feasibility -> Feasibility -> Pivotal -> Post-Marketing

- FIH: Safety
- Early Feasibility/Feasibility: Safety and early signals of efficacy, device improvement
- Pivotal: Safety and statistically significant efficacy
- Post-Marketing: Market/indication expansion



FDA Investigational Device Exemptions (IDEs)

- Required prior to clinical trials in the US for any “significant risk” devices
- Significant Risk
 - Intended as an implant and presents a potential for serious risk to the health, safety or welfare of a subject
 - Purported or represented to be for use supporting or sustaining human life and presents potential for serious risk to the health, safety or welfare
 - Substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare
 - Otherwise presents a potential for serious risk to the health, safety or welfare
- Honestly, most devices require an IDE. Drugs require an “IND”.



Trials in Australia

- Most devices only require ethics committee approval (very high risk = TGA CTA)
- Australia has an R&D rebate (43.5% on all trial expenses)
- Information is accepted by FDA up to early feasibility or feasibility stage
- Very popular destination for US medical device companies
- HREC = Australia, IRB = USA



Advice + Deadly Mistakes

- Avoid working with hospitals or universities (20-50% premium)
- Avoid working with a CRO (20-30% premium)
- Avoid university funding or investigator-initiated studies (you lose all IP = no VC funding)
- Must be extremely strategic in what the trial helps you achieve
- You need to be responsible for your own trial design. Get advice from the best, but realise that they do not understand your product as well as you do.
- Source trial protocols from similar products. Read them all and figure out best practices. Copy shamelessly.
- Learn how to write your own trial. Most physicians have no idea how to write one.
- Grants = free money, requires 12-24 months' notice (might kill your company)
- Consider seed funding (10-20% of company) or funding it yourself



FDA Meetings

Voluntary meetings - FDA are generally very keen to meet startups.

Requires a lot of preparation from startup perspective (hire a reg. consultant, \$10-20K)

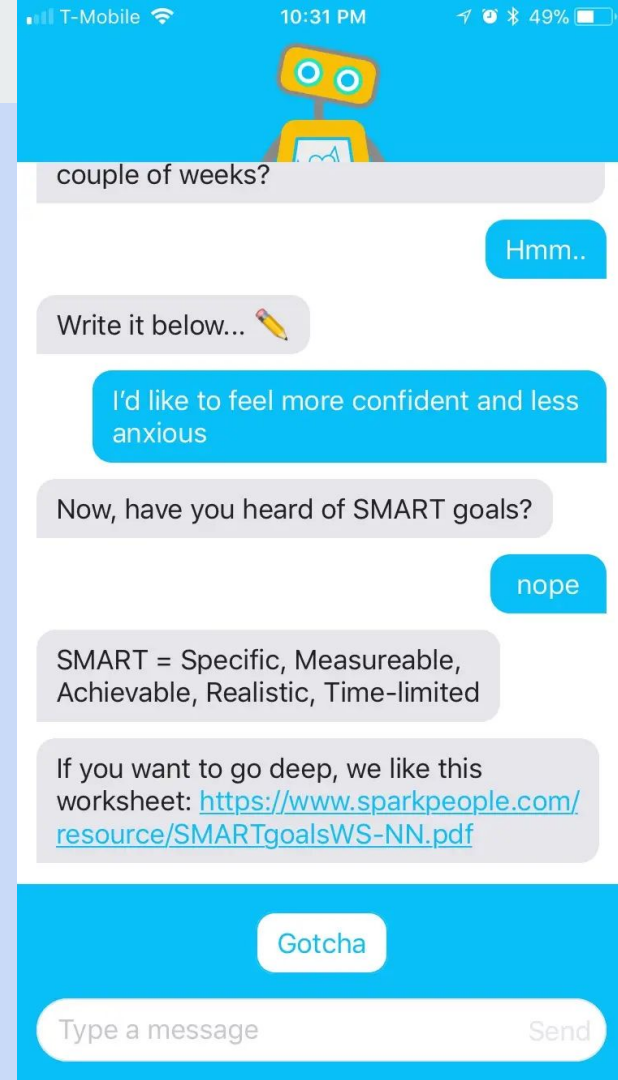
Available meeting types (3 months to schedule):

- **Pre-Subs:** FDA feedback prior to a submission (IDE, 510k, De Novo, PMA)
- **Sub Issue Requests:** Discuss an issue in a submission
- **Study Risk Determination:** Determine whether you need an IDE
- **Informational Meeting:** Present new tech to FDA, FDA mostly listens
- **Informal Meetings:** Teleconferencing/emails (general/simple qs)

Vignette 1

You have created a mental health app where a chatbot talks to anxious people. Which regulatory pathway would you choose and why?

- Device Registration
- Standard 510k
- De Novo 510k
- PMA
- Special 510k
- Abbreviated 510k



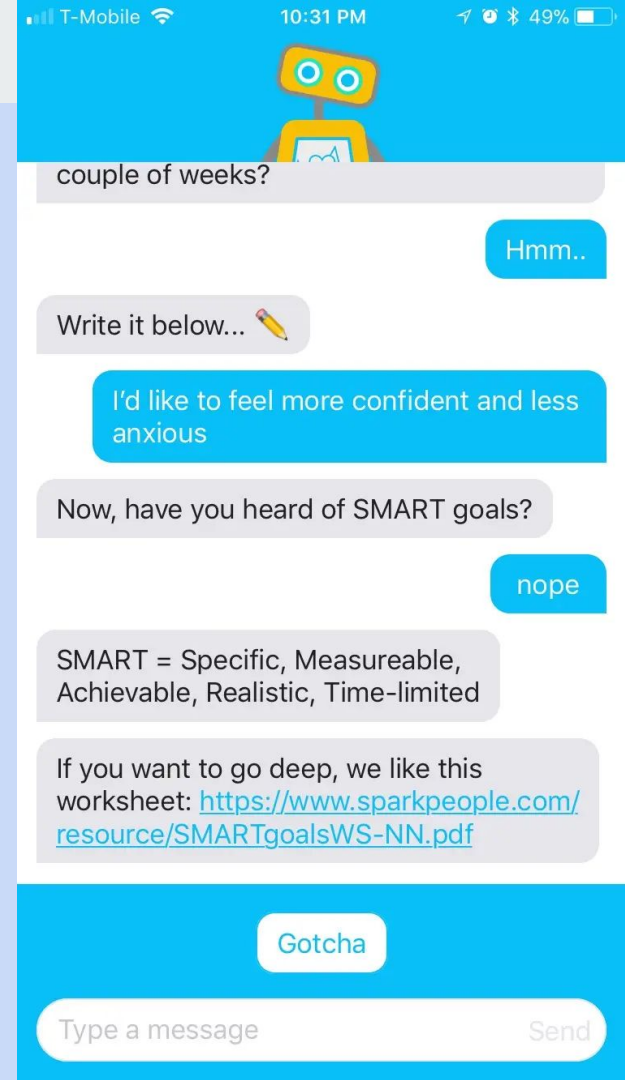
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If only claiming wellness, no need for rego. However, most well-informed companies will do at least Class I (as it is easy and allows you to have medical claims).

Could also consider 510k if there is something similar on the market. Slower pathway but stronger claims/higher BTEs



Vignette 2

You have created a novel device which solves aging (without predicate). Which regulatory pathway would you choose and why?

- Device Registration
- Standard 510k
- De Novo 510k
- PMA
- Special 510k
- Abbreviated 510k



Vignette 2

You have created a novel device which solves aging (without predicate). Which regulatory pathway would you choose and why?

- Device Registration
- Standard 510k
- De Novo 510k
- PMA
- Special 510k
- Abbreviated 510k

Depends on risk, but either De Novo or PMA. De Novo is faster to market and significantly cheaper. If you want to cripple your competitors and have enough time/money/resources, consider PMA.





Device Standards

Every device needs to adhere to regulatory engineering standards (IEC/ISO).

Provide FDA/CE mark evidence by testing at a certified lab (final product only).

Ethics committees will ask for some evidence of this (not comprehensive).

IEC standards are hilariously expensive. Buy the English multi-user versions from Estonia.

All devices need to cover biocompatibility, electrical/mechanical safety and EMC standards.

All devices must adhere to a primary standard and relevant secondary standards.

Biocompatibility Standards

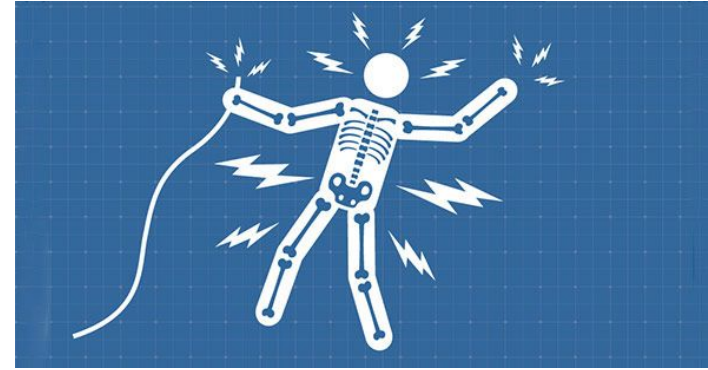
Depending on body contact level, need to do specific lab tests with material you're using

Refer to "Use of ISO 10993-1" from FDA

Medical device categorization by			Biological effect												
Nature of Body Contact		Contact Duration A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – permanent (> 30 d)	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental Toxicity	Degradation
Category	Contact														
Surface device	Intact skin	A	X	X	X										
		B	X	X	X										
		C	X	X	X										
	Mucosal membrane	A	X	X	X										
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O			
	Breached or compromised surface	A	X	X	X	O	O								
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O	O		
External communicating device	Blood path, indirect	A	X	X	X	X	O			X					
		B	X	X	X	X	O	O		X					
		C	X	X	O	X	O	X	X	O	X	O	O		
	Tissue/bone/dentin	A	X	X	X	X	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Circulating blood	A	X	X	X	X	O		O		X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		
Implant device	Tissue/bone	A	X	X	X	O	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Blood	A	X	X	X	X	O		O	X	X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		

Electrical/Mechanical Safety

Primary: IEC 60601-1



- **Electrical:** Type I/II, Type B/F/BF, leakage current (touch, pt, earth), HIPOT, SFCs
- **Mechanical:** Moving parts, instability, weight, stuck fingers, etc.
- **Radiation:** XR, Gamma, Microwave, Lasers, Infrared, Ultraviolet
- **Others:** Environmental, fire/flammability, overflow, disinfection/sterilisation, usability

Early-Stage = Highest Risk (usually leakage current, HIPOT, radiation)

Later-Stage = Cover everything

Electromagnetic Compatibility (EMC)

Primary: IEC 60601-1-2



- **EM Interference (Emissions Testing):** Your device impacts others
 - Conducted Emissions: Your device sends energy to grid and disrupts.
 - Radiated Emissions: Your device emits electromagnetic energy and disrupts.
 - Others: Harmonic Current, Voltage Flicker
- **EM Susceptibility (Immunity Testing):** Other devices impact yours
 - Conducted Immunity: Grid disturbances disrupt your device.
 - Radiated Immunity: EM energy disrupts your device.
 - Others: Electrical Discharge (Sparks), Electrical Fast Transient (Inductive Loads), Surges, Magnetic Fields, Voltage Dips/Drops

Early-Stage: Risk-Based (maybe conducted/radiated emissions and immunity)



Software Standards (IEC 62304)

Three safety classes:

- **Class A:** Cannot contribute to a hazardous situation or can contribute to a hazardous situation which does not result in unacceptable risk after consideration of risk control measures external to software system.
- **Class B:** Can contribute to a hazardous situation which results in unacceptable risk after consideration of risk control measures external to software system and resulting possible harm is non-serious injury.
- **Class C:** Can contribute to a hazardous situation which results in unacceptable risk after consideration of risk control measures external to software system and resulting possible harm is death or serious injury.

A higher class requires greater documentation for software verification/validation.



Software Standards (IEC 62304)

Software documentation	Class A	Class B	Class C
Software development plan	X	X	X
Software requirements specification	X	X	X
Software architecture		X	X
Software detailed design			X
Software unit implementation	X	X	X
Software unit verification		X	X
Software integration and integration testing		X	X
Software system testing		X	X
Software release	X	X	X



Medical AI Regulation

Still an evolving field, however approved AI software is becoming more common (178 as of latest update)

Classification: 84% Standard 510k, 13% De Novo, 3% PMA

Good ML Practices (US and UK)

- Multidisciplinary expertise is used during product life-cycle
- Study participants and datasets are representative of intended patient population
- Reference datasets are based on upon best available methods
- Focus is placed on the performance of the human-AI team
- Users are provided clear, essential information
- Good software engineering and security practices are implemented
- Training datasets are independent of test sets
- Model design is tailored to the available data and reflects the intended use
- Testing demonstrates device performance during clinically relevant conditions
- Deployed models are monitored for performance and retraining risks are managed

Quality Management System (QMS)



All device companies need to have a QMS. Spreadsheets <-> Specialised Software

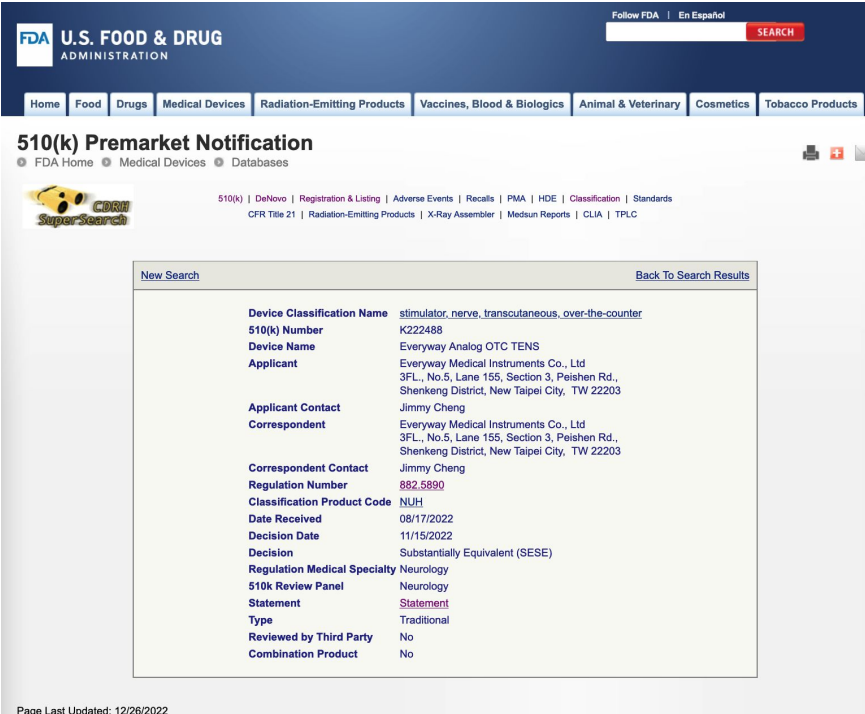
- **Design Input:** List of all product requirements, based on a lot of company/user research/prior studies, covers performance/safety/intended use/usability/marketing/regulatory/reimbursement/packaging/sterilisation requirements
- **Hazards/Risk/FMEA Analysis:** Procedural step > failure mode > root causes > potential harm > severity (SEV), occurrence (OCC), Risk Priority Number (SEV x OCC), Risk Mitigation
- **Verification:** Verify that you completed the processes you said you would
- **Validation:** Validate that the device works as intended

Recommendations

- Don't formally start this until you reach early feasibility stage (expensive and time-consuming).
- At FIH stage, just keep documentation for risks and inputs (informal).
- Big companies just use giant spreadsheets. Just get a bunch of experts together and discuss.

FDA Website Navigation

- **Product Codes:** Look for predicates
- **MAUDE:** Adverse events from similar devices
- Specific Classification Databases (e.g. 510k)
- Guidance Documents
- Specific Devices
- Instructions for Use (not on FDA)



FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español **SEARCH**

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

510(k) Premarket Notification

FDA Home Medical Devices Databases

510(k) | De Novo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

SuperSearch

[New Search](#) [Back To Search Results](#)

Device Classification Name	stimulator, nerve, transcutaneous, over-the-counter
510(k) Number	K222488
Device Name	Everyway Analog OTC TENS
Applicant	Everyway Medical Instruments Co., Ltd 3FL., No.5, Lane 155, Section 3, Peishen Rd., Shenkeng District, New Taipei City, TW 22203
Applicant Contact	Jimmy Cheng
Correspondent	Everyway Medical Instruments Co., Ltd 3FL., No.5, Lane 155, Section 3, Peishen Rd., Shenkeng District, New Taipei City, TW 22203
Correspondent Contact	Jimmy Cheng
Regulation Number	882.5890
Classification Product Code	NUH
Date Received	08/17/2022
Decision Date	11/15/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Neurology
510k Review Panel	Neurology
Statement	Statement
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

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