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Review Article

A Comparative Study Medical Device Dossier Of UGANDA And USA

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ABSTRACT

This study provides a comprehensive comparison of the medical device dossier requirements in Uganda and the United States, highlighting the regulatory frameworks, submission processes, and compliance standards. By examining the regulatory agencies—the Uganda National Drug Authority (NDA) and the U.S. Food and Drug Administration (FDA)—the research identifies key differences and similarities in their approaches to medical device approval. The study delves into the classification systems, dossier content requirements, and review timelines, emphasizing how these factors impact market entry and compliance for medical device manufacturers. Special focus is given to the harmonization efforts and the role of international guidelines, such as those from the International Medical Device Regulators Forum (IMDRF), in shaping local regulations. Through a qualitative analysis of regulatory documents, interviews with regulatory experts, and case studies of specific medical device approvals, the research offers insights into the challenges and opportunities faced by stakeholders in both countries. The findings aim to inform regulatory bodies, manufacturers, and policymakers, promoting better understanding and potential improvements in the regulatory landscapes to enhance patient safety and innovation in medical device technology.

INTRODUCTION

Definition:

A medical device mean any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings and animals for one or more of the specific medical purpose.

About NDA (National Drug Authority):

National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act

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established a National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.(1) The control of surgical instruments and appliances will be based on risk assessment and risk management such that the level of regulatory control applied to them is proportional to the degree of perceived risk associated with the surgical instrument and appliance. The requirements of the review process differ for each class, type and technology of the appliance.(1)

Introduction of USA:

The FDA's Center for Devices and Radiological Health (CDRH) oversees the regulation of companies involved in producing, packaging, labeling, and importing medical devices available for sale in the US. Furthermore, CDRH is tasked with regulating electronic products that emit radiation, including medical equipment like lasers and x-ray systems, as well as non-medical devices such as microwave ovens and color televisions.

CDRH role in Medical device:

CDRH places every kind of equipment into the proper class according to the regulatory control requirements (Class I: merely general controls; Class II: standards; and Class III: premarket approval).

OBJECTIVE:

The objective of this study is to conduct a comprehensive comparison of the regulatory requirements for medical device dossiers in Uganda and the United States Food and Drug Administration (USFDA). This comparison will focus on regulatory framework, dossier requirement, market dynamics, technical documentation, and approval process.

DISCUSSION:

MEDICAL DEVICE DOSSIER IN UGANDA:

Overview:

Surgical instruments and appliances will undergo classification according to a risk assessment and management framework. Regulatory oversight will correspond to the perceived risk level of each device, ensuring a proportional approach. The review process varies depending on the class, type, and technological complexity of the appliance, tailored to meet specific requirements.(2)

Market cap of UGANDA

Market	Year
10.705 billion $	2021
10.197 billion $	2020
9.795 billion $	2019

- Revenue in the medical devices market in Uganda is projected to reach US$118.90m in 2024.
- The market largest market is Cardiology Device with a project market volume of US$18.56m in 2024.
- Revenue is expected to show an annual growth rate (2024-2028) of 7.57%, resulting in a market volume of US$159.20m by 2028.
- In global comparison, most revenue will be generated in the United States US$182.0bn in 2024.

Device classification:

The classification of medical devices is essential to ensure their safety, efficacy, and quality. In Uganda, the National Drug Authority (NDA) is responsible for regulating medical devices. The risk-based classification system categorizes medical devices based on the potential risk they pose to patients and users. This document outlines the criteria and classes used in the classification of medical devices in Uganda.(1)(3)

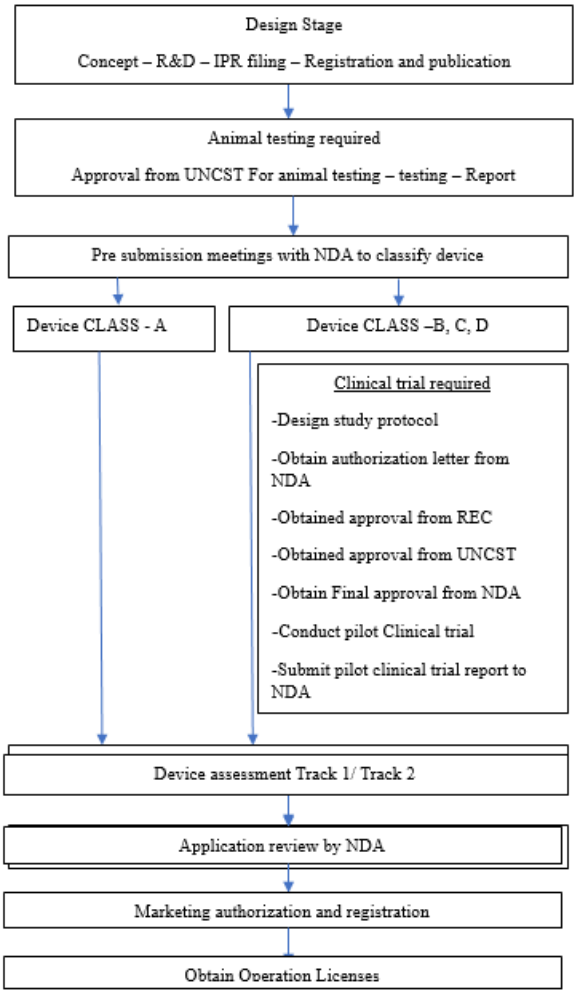
Classification	Level of risk	Example
Class A	Low risk	Surgical gloves / tongue depressors

Class B	Low – moderate risk	Hypodermic needles / suction equipment
Class C	Moderate – high risk	Lung ventilator / bone fixation plate
Class D	High risk	Heart valves / implantable defibrillator

Application processing required document:

- Accurately detail application letter (Hard copy & soft copy)
- Bank deposit slip (prove of payment)
- Sample of the product (if applicable)
- Documentation / Dossier
- Prior market history and approval

Registration flow chart:



Product registration dossier required technical document:

CLASS A	CLASS B,C,D
The filed application form	The filed application form
Letter of Authorization	Letter of Authorization
	Information on appliance details

IFU (instruction for use), patient information leaflet and promotion material (including brochure and catalogues)	Summary of technical documentation
Labeling information	Labeling information
Information of sterilization method (s) and validation standards used (where applicable)	Evidence of conformity of essential principles / essential requirements checklist of dossier
Proof of quality management system (QMS) e.g ISO 13485 certificate.	Proof of quality management system (QMS) e.g ISO 13485 certificate.

Example of dossier format:

Sr. No.	**Content**
Section 1	**Administrative and Legal Document**
1.1	Application form
1.2	Cover letter
1.3	Product Manufacturing license
1.4	Declaration of conformity
1.5	Proof of Quality Management System
1.6	Application Submission Checklist
Section 2	**Device Details**
2.1	Name
2.2	Description
2.3	Category
2.4	Class of Medical Device
2.5	Intended Use
2.6	Instruction for Use
2.7	Contraindication
2.8	Warnings
2.9	Precaution
2.10	Adverse effect
2.11	Storage Condition
2.12	Recommended shelf life
Section 3	**Summary of Technical Documentation**
3.1	Device description and features
3.2	Materials
3.3	Device Specification
3.4	Device verification / validation

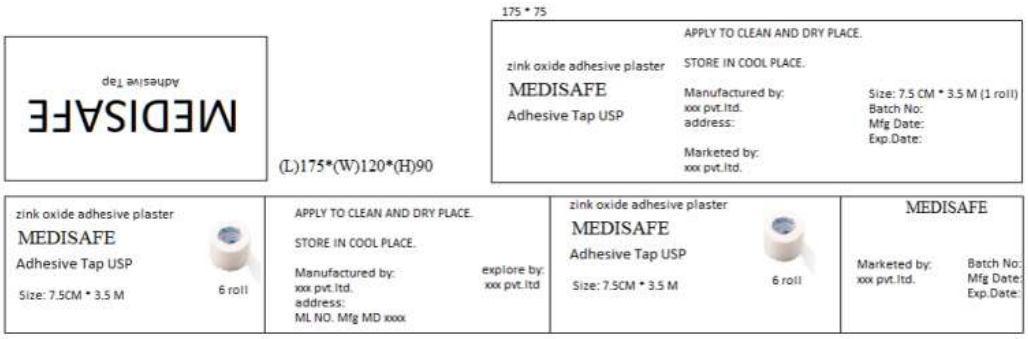
	I	Declaration / certificates of conformity to the recognized standards listed
Sr. No.	**Content**	
	II	Method of Analysis

	III	COA
3.4.1	Method of sterilization and sterilization validation summary report	
3.4.2	Shelf life the device	
3.5	Bio – compatibility	
3.6	Pre Clinical studies (if applicable)	
3.7	Clinical Evidence (if applicable)	
3.8	Manufacturing information	
Section 4	**Labelling Requirements**	

Labelling requirement:

i. provided in English,
ii. in a permanent and prominent manner,
iii. Legible and
iv. in terms that are easily understood by the intended user.

Example of label:



MEDICAL DEVICE DOSSIER IN USA:

Market cap in USA

The U.S. medical devices market is anticipated to grow from $192.78 billion in 2023 to $291.04 billion by 2030, at a CAGR of 6.1% during the forecast period. According to the U.S census bureau report, by 2060, the number of patient suffering from diabetes is projected to increase by 25.1% to 162 million.(8)

Device Classes and Regulatory Oversight:

1. Class I General Controls

With Exemptions
Without Exemptions

2.Class II General Controls and Special Controls

With Exemptions
Without Exemptions

3.Class III General Controls and Premarket Approval(9)

510(k) Notification:

Any individual looking to market a Class I, II, or III device in the US, intended for human use, and not requiring a Premarket Approval application (PMA), must file a 510(k) with the FDA, unless the device falls under an exemption from 510(k) requirements as specified in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and complies with the limitations outlined in .9 of the relevant device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9).(10) A 510(k) is a submission made to the FDA before marketing a device. It's meant to show that the device is similarly safe and effective, or substantially equivalent, to an already legally marketed device as per Section 513(i)(1)(A) of the FD&C Act.(10)

The submitter must wait until they receive an order confirming that the device is substantially equivalent (SE) before proceeding with marketing. Upon receiving the SE determination, the device can then be marketed in the US. Typically, the SE determination is made within 90 days based on the information provided by the submitter.

510(k) Required when:

1. Any new device market in first time
2. Substantial change
3. Change in intended use
4. Different technological characteristic
5. Combination product

510 (k) Submission process:

Acknowledgement of receipt:

You can submit your 510(k) application by sending either an e-STAR or an e-Copy.(10) Once you submit your 510(k) application to the FDA, they assign it a unique control number upon receipt. This number, known as the "510(k) number" or "K number," starts with the letter "K" followed by six digits.(10) The last four digits represent the sequential submission number for that year, starting with 0001 and increasing with each succeeding submission, while the first two digits indicate the calendar year the submission was received.

"KXXZZZZ"

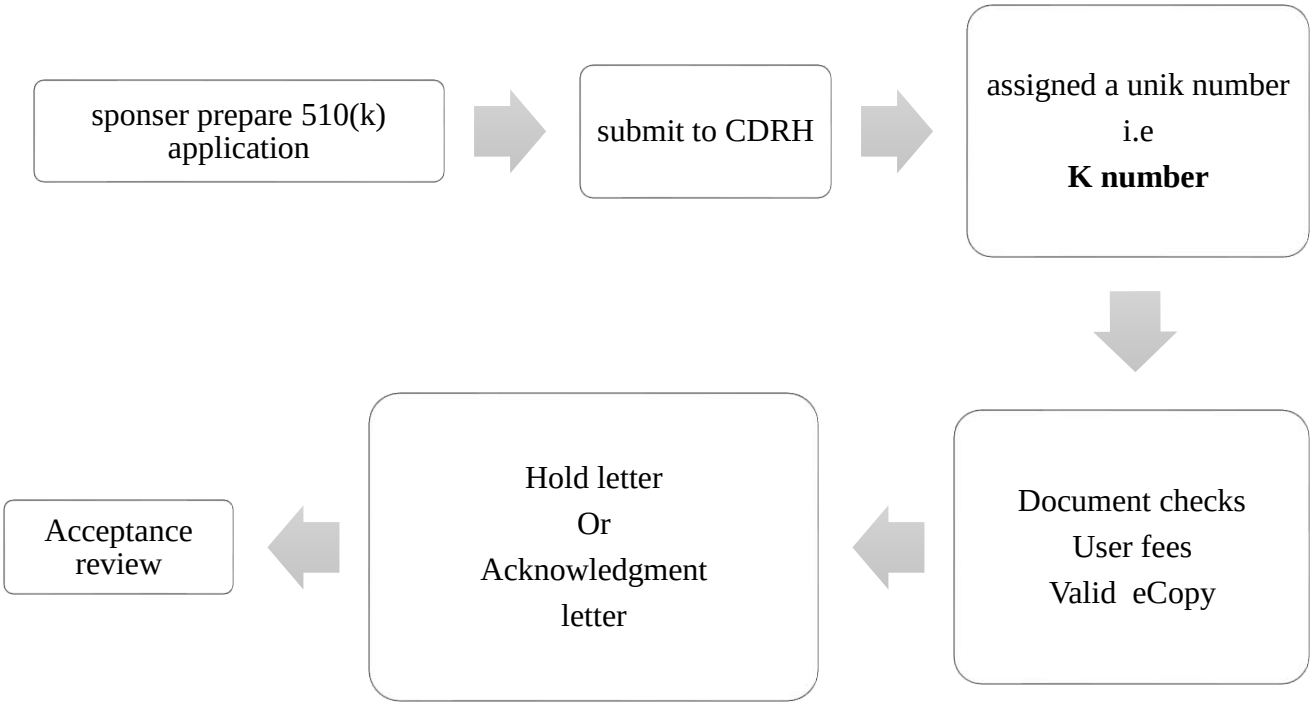
Where, K = 510(k)

XX = years of submission

ZZZZ = sequence number

For example: the first 510(k) submission for calendar year 2022 is "K220001"

510(k) Submission process flow chart:



Pre-market approval:

The FDA's premarket approval (PMA) process involves a thorough scientific and regulatory review to assess the safety and efficacy of Class III medical devices. Class III devices are categorized as those crucial for supporting human life, significantly preventing health impairments, or posing a potential and unacceptable risk of illness

or injury The regulation for premarket approval is found in Title 21 of the Code of Federal Regulations (CFR), Part 814, which covers Premarket Approval of Medical Devices.

When PMA is required:

Class III devices, which are classified under the strictest regulatory category for medical devices, are subject to PMA criteria. The Product Classification Database can be used to find product classifications for devices. The device name, classification, and, if available, a link to the pertinent section of the Code of Federal Regulations (CFR) are included in the database search results. The device type name, device ID, and categorization data are all listed in the CFR.

The CFR provides a regulatory number for Class III devices that were sold before the Medical Device Amendments of 1976. Use the three-letter product code to check the Premarket Approval (PMA) and the 510(k) Premarket Notification databases if you're not sure if the unclassified device needs a PMA. Furthermore, a new type of device may not be found in the product classification database. If the device is a high risk device, (Supports or maintains human life, is critically important in preventing health impairments, or poses a significant and unreasonable risk of illness or injury) Before being commercialized in the United States, a device must receive an approved PMA if it is found to be not substantially equivalent (NSE) to a Class I, II, or III [Class III needing 510(k)] device. Nevertheless, some devices may be eligible for the De Novo process to be classed as a Class I or Class II device if it is determined that they are not substantially equivalent to a certified Class I, II, or III (not requiring PMA) device.

Labelling:

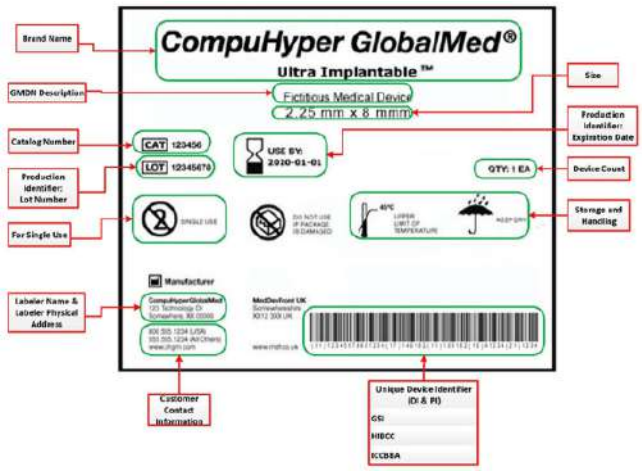
Define 'labeling' as a:

First of all, let's establish what labeling is and what it isn't. Labeling is written, printed, or graphic matter affixed to or associated with a medical device that is related to its identification, technical description, or use.

Documents

On or Accompanying the Device	Promoting the Device
Symbols or words on the device itself	Web video tutorials or user training modules
Instructions for use (IFU)	Marketing materials, including social media posts, web pages, sales videos, and press releases
Maintenance or safety manuals	
Packaging: pouch, box, or carton label	

Example of US labelled:



UDI requirement:

Sr. No	Importance document
1	Be issued under a system operated by FDA or an FDA-accredited issuing agency.
2	ISO/IEC 15459-2

3	ISO/IEC 15459-4
4	ISO/IEC 15459-6
5	Use only characters and numbers from the invariant character set of ISO/IEC 646

COMPARISON:

S.NO	Point of comparison	UGANDA	USA
1	Regulation authority(s)	NDA	USFDA
2	Classification categories	Class A	Class I
		Class B	Class II
		Class C	Class III
		Class D	
	Regulatory pathways	NDA	510 (K)
			Pre market approval (PMA)
	Fees for available pathways	First registration US $1500	MDUFA FY 2024
			510(K) $21,760
			PMA $ 4,83,560
	Quality Management Systems requirement	ISO 13485 certification	21 CFR part 820
	Assessment of technical data performed by	NDA	USFDA
	Medical Device Regulations	NDA Guidelines.	21 CFR part 800
			21 CFR part 801
			21 CFR part 803
			21 CFR part 806 to 21 CFR part 810
			21 CFR part 812
			21 CFR part 814
			21 CFR part 820
			21 CFR part 821
			21 CFR part 822
			21 CFR part 830
8	Validity of License	5 years	Annual establishment: Registration is required
9	Labelling Requirements		
		As per NDA guidelines	As per CFR part 801
	Document	Yes\No	Yes\No
	Device identification: name, description, and / or intended use	Yes	Yes
	Manufacturer identification: name and full address	Yes	Yes
	Lot number or serial number	Yes	Yes
	Unique Device Identifier (UDI)	No	Yes
	Manufacture or use-by date	Yes	Yes
	Name and address of in-country representative	If applicable	Yes
	Substance warnings	If applicable	Yes
	Storage or handling instructions	Yes	Yes
	Statement that product is a medical device	No	Yes

	Warnings or precautions	Yes	Yes
	Indication that device is sterile, single-use, or custom-made	Yes	Yes
	Device measurements, quantities, etc.	Yes	Yes
10	Data Presentation (Electronic/ Paper)	Electronic	Electronic/paper
11	Dossier Document		
	Application form	Yes	Yes
	Cover letter	Yes	Yes
	Product manufacturing license	Yes	Yes
	Device description	Yes	Yes
	Indication for Use	Yes	Yes
	Classification	Yes	Yes
	Predicates and Substantial Equivalence	No	Yes(510k)
	Software/Firmware	No	Yes(510k)
	Electromagnetic Compatibility (EMC), Electrical, Mechanical, Wireless and Thermal Safety	No	Yes
	Non clinical data	Yes	Yes
	Clinical data	Yes	Yes (PMA)
12	Final Outcome of Review Process	IMDRF member country clearance	Approval letter (PMA)
		NDA approval	Marketing clearance 510 (K)

CONCLUTION

The comparative study of medical device dossier requirements between Uganda and the USA highlights several key differences in regulatory frameworks, underscoring the need for Uganda to enhance its regulatory guidelines to ensure better compliance and patient safety. To improve regulatory compliance and ensure the safety of medical devices, Uganda needs to update and revise its guidelines, making them more specific and comprehensive. By considering international guidelines such as those from the International Medical Device Regulators Forum (IMDRF), Global Harmonization Task Force (GHTF), and the US FDA, Uganda can enhance its regulatory framework. Implementing these improvements will align Uganda's regulations with global standards, thereby enhancing the safety, efficacy, and quality of medical devices available in the country.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article.

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