BUTTON

NEWSLETTER ON MEDTECH AND FDA

Volume 1 September 2022

Our monthly MedExplorer newsletter can help you predicate 510k clearance time and explore new MedTech features for your next iteration in product development.

If you want to have more information to optimize product design and FDA pathways, please contact us at contact@buttontech.us.

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In this newsletter, we want to showcase BUTTON's digital system called Medical Device Analyzer. It is a self-assessment tool that helps medical technology companies estimate their FDA application status (especially for 510(k)), explore possible new features, evaluate product competition, seek company partnership opportunities, and obtain potential manufacturing improvement information.

Let us showcase these features with one commonly-used FDA product code for 510(k) medical devices:

- MUH: System, X-Ray, Extraoral Source, Digital

By putting in the product code in mind, the user can quickly estimate clearance time length for a product or explore potential new features.

1 Estimate Clearance Time Length for A Product

The engine developed by BUTTON predicates the possible clearance time window for medical device with Product Code of "MUH". The results are shown in Figure 1 and Figure 2.

Figure 1 510K Submission Scenario

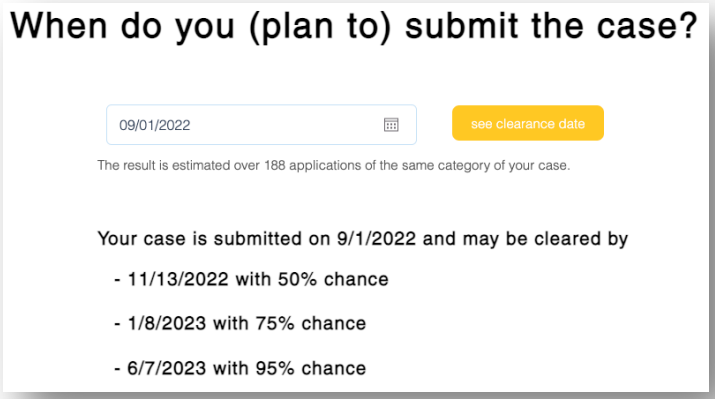

Figure 2 Distribution of Processing Days

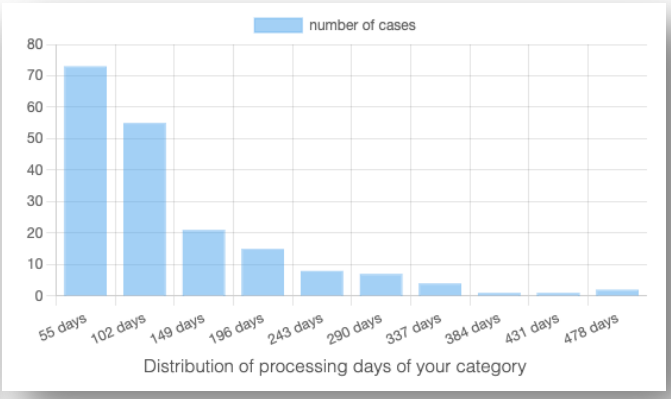

Figure 3 lists the cases cleared most recently for Product Code "MUH".

Figure 3 Cases Cleared Most Recently

510K submissions with this Classification Product Code cleared most recently:

APPLICANT	COUNTRY	CLEARANCE DATE	PROCESSING DAYS	DEVICE NAME
REALCLOUD IMAGING INC DBA REALCLOUD IMAGING	US	8/31/2022	57	Brasseler GEM, Brasseler GEM10, Brasseler GEM15, Brasseler GEM2(
SHANGHAI HANDY MEDICAL EQUIPMENT CO. LTD	CN	6/22/2022	78	HDR Sensor- HDR361 (Size 1), HDR Sensor- HDR461 (Size 2)
GENORAY CO. LTD	KR	5/19/2022	94	PAPAYA & PAPAYA Plus
DENTIMAX INC	US	4/13/2022	44	OpenSensorX Series
IRAY TECHNOLOGY TAICANG LTD	CN	3/11/2022	25	Dental sensors NanoPix1, NanoPix2

2 Explore Potential New Features for A Product

In order to make products more competitive, companies usually add or integrate multiple functionalities into one product. With big data analysis technology, our database is able to help you **quickly identify** what functionalities other companies have added to their products that are similar to yours.

Table 1 summarizes a **partial** list of possible other features for devices with Product Code MUH. In this table we do not directly describe such functionalities or features. Instead, we use the language of FDA standard product classification and list the names of device definitions that have these as their main features or functionalities, in order to make them more standardized and compatible with FDA submission and regulation.

Contact us at contact@buttontech.us to know the full list with more detailed device information.

Table 1 Possible Other Features for Devices with Product Code MUH

DEVICE NAME	DEVICE CLASS	FEATURE DESCRIPTION
Cephalometer	class-2	The product with this feature is regulated by FDA as Cephalometer., which is identified as: A cephalometer is a device used in dentistry during x-ray procedures. The device is intended to place and to hold a patient's head in a standard position during dental x-rays.
Unit, X-Ray, Extraoral With Timer	class-2	The product with this feature is regulated by FDA as Extraoral source x-ray system., which is identified as: An extraoral source x-ray system is an AC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.
System, X-Ray, Tomography, Computed	class-2	The product with this feature is regulated by FDA as Computed tomography x-ray system., which is identified as: A computed tomography x-ray system is a diagnostic x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
System, Image Processing, Radiological	class-2	The product with this feature is regulated by FDA as Medical image management and processing system., which is identified as: A medical image management and processing system is a device that provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis, or patient management. The software components may provide advanced or complex image processing functions for image manipulation,
Solid State X-Ray Imager (Flat Panel/Digital Imager)	class-2	The product with this feature is regulated by FDA as Stationary x-ray system., which is identified as: A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

3 Contact Us for Customized Business Intelligence Analysis

Please contact us at contact@buttontech.us if you are interested in getting to know about FDA Medical Device Information in more details, such as:

- **Competition challenges and cooperation opportunities;**
- **A proper FDA-registered contractor manufacturer;**
- **Other customized business intelligence analysis.**