Team 12

BME 180/EngrMSE 189: Fall 2019 Quarter Senior Design

Homework # 3 (total 120 pts)

Patent and Background Search

Assignment

1. (20 Points) 510K vs. PMA

Give a detailed explanation of what a PMA (Pre-market Approval) is. Give a detailed explanation of what a 510K is. Explain the differences between the two. Provide reasons as to why a 510K would be filed as opposed to a PMA.

A PMA is a regulated process by the FDA to assess the safety and efficiency of a Class III medical device [1]. A Class III medical device is one that physically supports life, is an implant, or demonstrates a risk of illness or injury [2]. Because of the level of risk that Class III medical devices are associated with, a PMA is required to be filed. Of all device marketing applications provided by the FDA, the PMA is the most strict. There must be sufficient scientific proof that the device is safe to be on the market before the PMA is approved. The filer of the PMA is the person who has the rights of the data that is used during FDA approval [1].

One can search for device product classifications for the PMA on the Product Classification Database, which provides the name of the device, classification, and Code of Federal Regulations (CFR). For devices marketed before 1976, there is a regulation number provided for Class III medical devices on the CFR. It will provide a date for when the PMA should be filed. If it does not provide a date, then a Class III 510(k) should be filed [1].

PMAs should include a technical section, non-clinical laboratories section, and clinical investigations section. The technical section can be divided into the non-clinical laboratory section and clinical investigations section and should contain data and information which allows the FDA to decide whether to approve the PMA or not. For the non-clinical laboratory section, information from bench work that does not involve human trials should be listed. For the clinical investigations section, data and information from human trials should be included [1].

A 510k should be submitted for Class I, Class II, and Class III medical devices for which a PMA is not required [4]. Class I medical devices have general control, while Class II medical devices have general and specific controls [3]. It should be submitted unless the device is excluded from submitting a 510k. A 510k does not come in a form, but

rather the requirements are described by 21 CFR 807. A device must be proven to be substantially equivalent to a previous device in order for the 510k to be submitted [4].

In order to prove substantial equivalence, a few requirements must be fulfilled. One way is to prove that a device has the same use as another device already approved by the FDA and uses the same technological attributes. Another way is to prove that it has the same use as another device, has different technological attributes but does not raise issues about safety and efficacy, and the data provided to the FDA shows that it is safe and effective [4].

There are some differences between a 510k and a PMA. If a device is sufficiently equivalent to a medical device already approved by the FDA, then a 510k would be required. It is processed between 30 to 90 days. Laboratory testing is usually a requirement, but human trials are not necessary. A PMA is more detailed than a 510k device, and the FDA has 180 days to approve it. It requires human trials [5]. A 510k does not require a form to fill out unlike a PMA [4].

Again, a 510K would be filed if the medical device is sufficiently equivalent to a medical device already approved by the FDA [4]. A 510k may also be filed if a Class I and Class II medical device is not excluded from filing a premarket notification [3]. In addition, a 510k would be filed if a Class III medical device does not require a PMA [1]. If a device which has been marketed before May 28, 1976 has been marketed for another use, then a 510k is required [4]. If it is similar to a device that has been marketed before May 28, 1976 but is marketed afterwards, a 510k is also required [4].

2. (10 Points) Your Device and the FDA

Based on your answer to (1), would your project be filing for a PMA or a 510K? Provide supporting reasons and preliminary information which justify your answer.

Our project would be filing for a 510k. It is a Class II medical device due to a slight risk when inhaling flavored air from the device. It is similar to a Class II medical device with a 510K already submitted called the SmartInhaler [6]. They share the same mechanism of breathing in a bottled substance. It also is wired to an app to monitor breathing rates. Data from device development will also be provided to prove its safety and efficiency.

3. (30 Points) Perform and Patent Search for your Project

Perform a thorough patent search with keywords through the U.S. PTO and provide a list of related patents.

(https://www.uspto.gov/patents-application-process/search-patents)

It is important to perform patent searches in other regions of the world as well. Search through the European Union Patents as well and provide the related patents (https://www.epo.org/searching-for-patents.html)

(Note: Eventually you may want to check the Chinese Patent Office as well, however checking this is...difficult at times due to firewalls and changing political issues as well as some translation barriers)

(https://www.epo.org/searching-for-patents/helpful-resources/asian/china/search.html)

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1. Breath sampling and analysis device, 10,458,992
2. Method and apparatus for purification and treatment of air,10,456,736
3. Droplet delivery device for delivery of fluids to the pulmonary system and methods of use,10,449,314
4. Humidification system, 10,449,323
5. Method and apparatus for vaporizing liquids or the like with a concealable vaporizer pen,10,448,456
6. Hand-held inhalable vapor producing device and method, 10,440,993

7. Inhalation device for powdered drugs, 10,434,268
8. AEROSOL GENERATING DEVICE AND HEATING CONTROL METHOD THEREFOR, WO2019196514
9. SYSTEMS AND METHODS FOR VAPORIZER ANALYSIS,US2019313697
10. VAPOUR PROVISION APPARATUS, MX2018011308
11. BREATHING DEVICE, WO2019183516
12. Aerosol inhalation system for respiratory medicine department, CN110064108
13. Flavor inhaler, accommodation case of flavor source unit, and ashtray with accommodation portion of flavor source unit, TW201912043 (A)
14. Breathing-controlled inhalation device for dry powder and method for even distribution of said dry powder in air, CN00813903

15. Inhalation device for dry powder controlled by inspiration, CN01823803
16. Healthy pleasurable inhalation device, CN200480040529
17. Inhaler device that reduces the risk for miscounting a dosage, CN200580022142
18. Connector for close type compressor and operating fluid inhalation device using same, CN200710085497
19. Dry powder inhalation device for the simultaneous administration of more than one medicament, CN200780008811
20. Oxygen inhalation device for relieving tachypnea of infant suffering from congenital heart disease, CN201210067745
21. Medicine inhalation device for upper respiratory tract, CN201310155004
22. Combined portable constant-temperature anti-bacteria humidifying oxygen-inhalation device with intelligent control function, CN201410337089
23. Housing for an inhalation device and inhalation device for orally administering a pharmaceutical medium, CN201480042040
24. Flow regulating inhaler device, CN201580045638
25. Aerosol inhalation device for respiration medicine, CN201610480490
26. FLAVORING ELEMENT FOR AN INHALATION DEVICE, CN201680032902
27. Electronic inhaling device, CN201710452774

4. *(30 Points) Stakeholder Analysis*

On projects, a stakeholder is a person with an interest or concern in the project. In academia, stakeholders can be professors, advisors (academic or industry), investors, subject matter experts, etc...The objective of the stakeholder analysis is to:

1. Identify the individual stakeholders and stakeholder groups who are critical to the success of the project.

2. Identify those who need to be informed or made aware of any project or key changes, to assess the current and desired commitment levels and areas of resistance for the identified stakeholders.

3. Provides a high-level action plan for ensuring stakeholders achieve the desired level of commitment and support.

Perform a stakeholder analysis by filling out the below table. You can use the following link to help you get started: http://ebiodesign.org/chapter/2-3-stakeholder-analysis/

Name of the Stakeholder or Group	Stakeholder's current level of Commitment	Desired level of commitment from the stakeholder	Level of change impact for the stakeholder	Description of change and its impact on stakeholders	Level of resistance for the stakeholder	Positive factors that may contribute to stakeholder commitment	Resistance factors that may impact negatively upon stakeholder commitment	Tactics and actions to be used to move the stakeholder from current to desired commitment level
Members of the Project	Committed	Commitment	High	Any change to any aspects of the project will have a high impact on this group.	High	Their role in the project and recognition for their contribution.	Uncooperative teammates, missed deadlines	Regular weekly meetings and clarification on responsibilities and roles.
Dr. Sean Young	Committed	Buy-in	Medium	Any changes to the processes, systems, and tools used during the lifespan of the project will have an effect on Dr. Young. For example, Dr. Young is our physician mentor and will be involved in actions or steps taken to ensure the success of the project. Therefore any changes to these processes will have an impact on him.	Medium	Trace accountability and record decisions/agreement	Lack of communication and failure to meet expectations.	Regular bi-weekly meeting and detailed progress report.
Dr. Michelle Khine	Committed	Buy-in	Medium	Any changes to the processes, systems, tools, job roles, and performance reviews during the lifespan of the project will have an effect on Dr. Khine. To emphasize, any changes to the systems in place will have a direct impact on Dr. Khine as she will need to help us with rearrangements and scheduling.	Medium	Desire for innovation	Lack of communication and failure to meet expectations.	Regular bi-weekly meeting and detailed progress report.
Wellness Investors	Unaware	Understanding	Medium	Any change to compensation, and budget aspect of the project will have an impact on investors. Any changes that will result in a decrease of revenue will have a direct impact on investors.	Medium	Regular Progress reports and showing how is resulting in value	Lack of consistency and project resulting in loss.	Regular Progress report
Customers	Unaware	Aware	Low	Any changes to the final product will have an impact on the external customers, such as design, price, and distribution.	Low	Product stability, safety, and cost	Lack of quality	Regular quality tests and market surveys.

5. (*30 Points) Market Analysis*

Not all needs are created equal. For better or worse, innovators must recognize that even seemingly important needs cannot be addressed unless there is a compelling, accessible market to support the effort and expense required to bring forward a new solution. To assess this, perform a market analysis by filling out the below table. You can use the following link and your above results from your patent search to help you get started:

To address the effects of stress on young adults, we conducted a market analysis. Our research showed a segment of the Global Corporate Wellness market which is in rise due to high stress work environments. This segment deals with different programs offered in corporates to manage the stress at work. This market has been estimated at USD 7.01 billion in year 2018 with CAGR of roughly 8.4%. [7],[8] With the collected data and use of CAGR calculator, we estimated the future market size to be at USD 135 billion in year 2026. [9]

Market size (current)	**Market size (future)**	**Market trends**	**Market growth rate**	**Key success factors**	**Main Competitors**	**Main Competitor Key Patents**
USD 7.01 billion in 2018 [7],[8]	USD 135 Billion By 2026 [7],[8]	Expanding [7],[8]	CAGR of 8.4% [9]	Access to Chinese manufacturers, international distribution, and progress on device development Design (progress on device development) Manufacturing (Access to Chinese manufacturers, international distribution, and reducing the manufacturing cost while maintaining the quality) Marketing (Social acceptance and trending) Customer satisfaction	HearthMath Women's Shift Aromatherapy Inhaler (Itson, TGE-V, Emporium Evolution, 0531 Aromatherapy Inhaler, Old School Aromatherapy Inhaler,) Nutrovape Turboforte Vectura AKITA® JET nebuliser Novartis' Ultibro® Breezhaler® Penthrox® Inhaler Syqe® Inhaler	Vectura Akita Jet Nebulizer: https://worldwide.espacenet.com/publicationDetails/biblio?II=9&ND=3&adjacent=true&locale=en_EP&FT=D&date=20120330&CC=PL&NR=1684834T3&KC=T3 Novartis' Ultibro® Breezhaler® https://worldwide.espacenet.com/publicationDetails/biblio?II=13&ND=3&adjacent=true&locale=en_EP&FT=D&date=20110831&CC=PL&NR=1747036T3&KC=T3 Penthrox® Inhaler http://patft.uspto.gov/netacgi/nph-Parse

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Works Cited

[1] U.S. Food and Drug Administration, “Premarket Approval (PMA),” U.S. Food and Drug Administration, 19-May-2019. [Online]. Available: https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma. [Accessed: 02-Nov-2019].

[2]U.S. Food and Drug Administration, “Learn if a Medical Device Has Been Cleared by FDA for Marketing,” *U.S. Food and Drug Administration*, 12-Dec-2017. [Online]. Available: https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing. [Accessed: 02-Nov-2019].

[3] U.S. Food and Drug Administration, “Classify Your Medical Device,” U.S. Food and Drug Administration, 31-Aug-2018. [Online]. Available: https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device. [Accessed: 02-Nov-2019].

[4] U.S. Food and Drug Administration, “Premarket Notification 510(k),” U.S. Food and Drug Administration, 27-Sep-2018. [Online]. Available: https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.[Accessed: 02-Nov-2019].

[5] Greenlight Guru, “Glossary: 510k vs PMA,” -Greenlight Guru. [Online]. Available: https://www.greenlight.guru/glossary/510k-pma. [Accessed: 02-Nov-2019].

[6] U.S. Food and Drug Administration, “510(k) Premarket Notification,” accessdata.fda.gov, 28-Oct-2019. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K180407. [Accessed: 03-Nov-2019].

[7] Grand View Research, “Workplace Stress Management Market Size: Industry Report, 2026,” *Workplace Stress Management Market Size | Industry Report, 2026*. [Online]. Available: https://www.grandviewresearch.com/industry-analysis/workplace-stress-management-market.

[8] Arizton Advisory & Intelligence, “Stress Management Segment in Corporate Wellness Market in US to Worth $1.7 Billion by 2023: Arizton,” *Arizton Advisory & Intelligence*, Feb-2018. [Online]. Available: https://www.arizton.com/news/press-release/us-corporate-wellness-market-share. [Accessed: 05-Nov-2019].

[9] M. Mucha, J. Mathison, and T. Jedynak, “CAGR Calculator (Compound Annual Growth Rate),” *Omni*, 23-Oct-2019. [Online]. Available: https://www.omnicalculator.com/finance/cagr. [Accessed: 05-Nov-2019].