MeDevice

Enhancing transparency of medical device communications to improve consumer accessibility

Brain Alliance

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Presentation Overview

- Background
- Our Solution
- Importance and Impact
- Implementation
- Closing Remarks

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Science Priority Areas

Section 8.

Strategic Plan for Regulatory Science

Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

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Transparency

"We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make."

- Center for Devices and Radiological Health

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Background


Walker


Pacemaker


Bed pan

Medical Device

"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."


Apple Watch


Catheter


Nebulizer


Breast Implant

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4,000

Number of devices tracked by the FDA

42.6%

The U.S. is the largest region in the global medical devices market

$88,980,000,000

Amount spent in the U.S. by 2018

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Problem

The FDA website has several tools to access information on Medical Devices, ranging from recalls to premarket approvals to registering a device

There is **no user-friendly tool** that synthesizes all of the information regarding medical devices

Current Apps for Medical Devices:

- SoftwareCPR
- Atlas of Medical Devices on Chest Radiography
- Endovascular Today Device Guide App

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Our Solution:
MeDevice

A mobile app that holds all information about your medical device

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App Icon & Splash Screen

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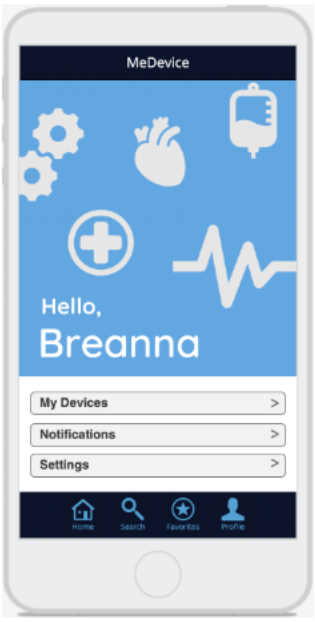
Profile



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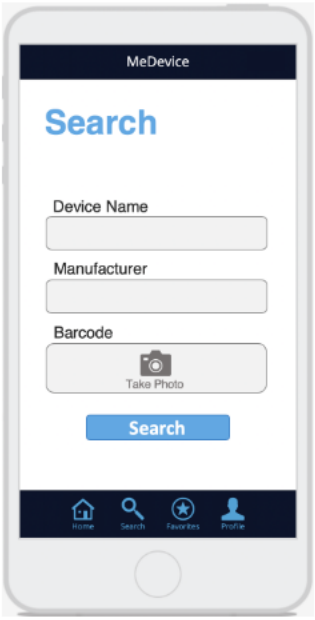
Search



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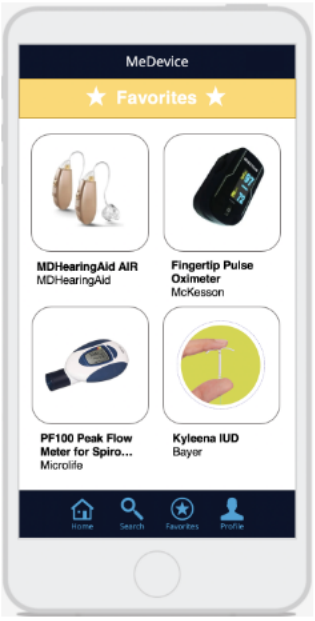
Favorites



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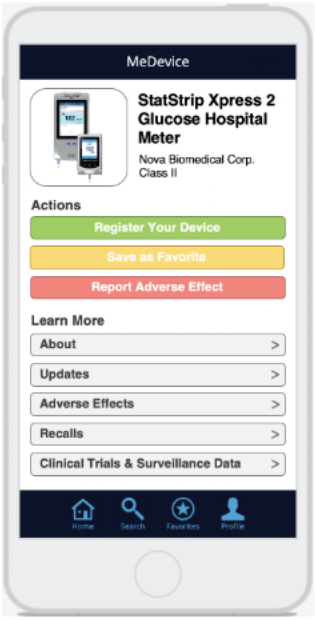
Medical Device Profile



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Impact and Importance

- Enhancing and promoting understanding of medical device use
- Fostering patient awareness and safety through an all-inclusive tool
- Impacting patients on a macro-level with ease of use, accessibility, and streamlined features

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MDIC and NESTcc

MDIC
The Medical Device Innovation Consortium

Current FDA partner that aims to advance regulatory science in the medical device industry

NESTcc
The National Evaluation System for health Technology Coordinating Center

MDIC initiative that aims to ensure the safety of medical devices through generating real-world evidence and innovative research

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Implementation

- All necessary medical device information currently exists in various FDA databases
- Investment: MDIC, Manufacturers and Healthcare Institutions
  - Promotes post-market surveillance
  - Ease device use

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Closing Remarks

MEETING

Public Meeting - Food and Drug Administration's Communications About the Safety of Medical Devices

APRIL 1, 2020

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THANKS!
ANY QUESTIONS?

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References

- https://www.fda.gov/science-research/advancing-regulatory-science/strategic-plan-regulatory-science
- https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-mission-vision-and-shared-values
- https://www.fda.gov/industry/regulated-products/medical-device-overview#What%20is%20a%20medical%20device
- https://www.globenewswire.com/news-release/2019/09/19/1918062/0/en/Global-Medical-Devices-Market-Report-2019-2022-A-521-Billion-Opportunity-Analysis.html
- https://www.globenewswire.com/news-release/2019/09/19/1918062/0/en/Global-Medical-Devices-Market-Report-2019-2022-A-521-Billion-Opportunity-Analysis.html
- https://www.fda.gov/medical-devices
- https://cms.appinstitute.com/cms/app_build.php#nav-images
- https://mockuphone.com/iphonexspacegrey
- https://iconsflow.com/editor
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=484700&lpcd=PZI
- https://www.cleveroad.com/blog/how-much-does-it-cost-to-create-an-app
- https://plaquepsoriasis.com/clinical/10-things-know-clinical-trials/
- https://existek.com/blog/app-development-timeline-how-long-does-it-take/
- https://www.businesswire.com/news/home/20190604006034/en/National-Evaluation-System-health-Technology-Coordinating-Center
- https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude
- https://mdic.org/about/mission-purpose/
- http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0

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