Elexes

Innovative Journey

Accelerating FDA Clearance for Next-Gen Blood Glucose Monitoring Device

About the Client

A medical device company pioneering the development of a point-of-care blood glucose monitoring device came to Elexes for expert guidance in securing a FDA 510(k) clearance for their device.

Elexes was interested in the project due to the challenges and the uniqueness of the device.

Device Overview

The client's innovative device featured a compact design, allowing users to monitor blood glucose levels conveniently. It included essential accessories like lancets, test strips, and a user-friendly interface for seamless operation. The device came in two configurations, catering to different user preferences and needs.


Major Milestones for
FDA Compliance
1
Pre-Submission Application
2
Testing Execution
3
Packaging and Labeling Compliance
4
Regulatory Submission Support
5
Post market compliance

1 Pre Submission Application

Understanding the critical nature of the FDA interactions, we initiated a Pre-Submission application to gain insights into the FDA's expectations early on. This process involved the following:

Application Preparation
We crafted a comprehensive document outlining the device, testing protocols, and proposed labeling.

FDA Interaction
We successfully secured a Pre-Submission meeting, engaging in a dialogue with FDA officials.

Key Questions
Addressed FDA questions on testing methodologies, clinical study design, and anticipated challenges.

2 Testing Execution

In order to save time, some testing execution began while the pre-submission was being pursued, while some was conducted after, especially the ones for which FDA's feedback was critical. While the overall execution went well, there were certain challenges that were encountered in the journey.

Challenges

Despite rigorous planning, certain challenges surfaced during testing.

- **Unexpected Variability:** Encountered unanticipated variability in test results during analytical performance testing.
- **Clinical Study Hurdles:** Faced recruitment challenges and unexpected dropouts in the clinical study, impacting the initially planned timeline.
- **Interference from External Factors:** External factors such as temperature, humidity, and interference from substances commonly found in the environment (e.g., ascorbic acid) at times impacted the device's performance.
- **Long-term Stability:** Verifying the long-term stability and durability of the blood glucose meter, including its components and software, ensuring its effective performance over an extended period was a challenge.

Solutions Suggested By Elexes

1

Adaptive Testing Protocols

Implemented adaptive testing protocols to address and overcome unexpected variability, ensuring robust analytical performance.

2

Clinical Study Optimization

Collaborated with the client to optimize the clinical study, overcoming recruitment challenges and adapting to unforeseen circumstances.

3

Harnessing design features to address interference from external factors

Based on risk analysis and observations from the testing, a cross functional discussion was hosted by Elexes to conclude that the design of the blood glucose meter has to be updated so that it is resilient to common environmental factors. Certain materials and components were utilized that are less susceptible to interference, and implement shielding mechanisms.

4

Multifactor approach for long term stability:

Implemented continuous monitoring systems that track the device's performance over extended periods. This allowed for the early identification of stability issues before they became critical.

Conducted accelerated aging studies during the device development phase to simulate the effects of long-term use. This helped identify potential issues related to materials degradation and performance decline.

Incorporated a feature to prompt users for regular calibration checks. This ensured that the device remains accurate and stable over time.

3

Regulatory Submission Support

Building on the Pre-Submission insights and addressing challenges, Elexes' regulatory affairs team provided comprehensive support for the 510(k) submission.

Compiled a detailed set of documents, incorporating testing outcomes, risk mitigation strategies, and the clinical study output.

Conducted a meticulous comparison with a predicate device, emphasizing how testing further demonstrated substantial equivalence.

Ensured that the 510k submission gets through to the FDA in one go, without received a Refuse to Accept (RTA).

4

Packaging and Labeling Compliance

Ensured that the packaging and labeling strategies aligned with the testing methodologies and outcomes, providing a transparent depiction of the device's capabilities and usage instructions.

5 Post market compliance

Registration and listing

Import of their product (contract manufactured outside the US) into US

Performed regular audits for continued compliance

Key Takeaway

13 Mistakes to avoid in 510(k) submission

Download to read now

Reducing Time-to-Clearance

To expedite the FDA clearance process, we implemented several strategies:

1

Proactive Communication

Maintained open communication channels with the FDA to promptly address questions and provide requested information.

2

Parallel Workstreams

Initiated parallel workstreams for document preparation and testing, reducing sequential dependencies.

3

Optimized FDA Response

Structured responses to FDA feedback in a concise and organized manner, facilitating a faster review process.

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Successful Outcome

The device's innovative design, compliant packaging, and labeling positioned it for a successful market entry.

Despite some unforeseen challenges, several mitigation strategies employed during testing, coupled with insights gained through the Pre-Submission application, led to a successful FDA 510(k) clearance.

Elexes

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