**Contact:** Jeremy Elias
**Phone**: (b)(6)
**Web**: TrackMySolutions.us

September 16, 2021

Dear FDA,

Thank you for the opportunity to provide written feedback and advice to the Commissioner of Food and Drugs, or designee, on complex scientific issues relating to medical devices, the regulation of devices, and their use by patients.

I am writing this letter on behalf of TrackMy Solutions as I am the Director of Community Outreach and Patient Advocacy. Our mission is to enhance patient safety and save lives through technology. We are a technology provider focused on making discrete medical record data accessible and actionable to improve overall health of patients.

Our company exists because of the issue surrounding medical device recalls and the lack of communication between the FDA, the manufactures, the medical community and most importantly, the patients with the implanted device. Our CEO, Jeremy Elias, developed TrackMy Solutions/TrackMy Implants because a family friend had a recalled device that the family was unaware of. Sadly, this friend lost his life and Jeremy made it his mission to help with management of implanted medical devices with communication and recall notification in real time the doctors, hospitals and patients.

A recent example of the problem is when some textured breast implants were recalled back in 2019 due to these implants causing cancer of the immune system (BIA-ALCL). Allergan, the manufacturer, had lost track of thousands of patients. Doctors were not easily aware of which patients had the recalled breast implants and patients were also unaware of which type were implanted.

As we work through this problem, we discovered that physicians, surgeons, hospitals and surgery centers rely on paper and this is not effective. Patients are confused and uniformed. It is time to solve this problem and bring this issue into the digital age.

Our solution is in existence today and can provide the following for patients:

- Provides electronic ID card, replaces paper card
- Facilitates obtaining UDI information for providers
- Automates patient and provider notification in the event of recall via preferred communication method (e.g., email, phone call)
- Submits adverse event report connected to UDI
- Tracks multiple devices per patient and preserves history as implants are removed
- Ability to designate power of attorney from account
- Provides implant history to the surgeon for improved surgical planning
- Alert patient and providers regarding MRI safety associated with devices

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We have discovered that our patients want:

- Trust & security
- To know if their device has been recalled with the ability to search
- To know what EXACTLY is implanted into their bodies
- Digital alerting notification for recalls in real time
- Adverse Event Reporting system that feeds to the FDA MedWatch
- Ability to monitor for others (caregivers, advocates)
- Quick check for MRI usage

We thank you for the opportunity to provide some feedback and advice. If you wish to discuss further, feel free to reach out to myself or our Founder and CEO Jeremy Elias.
https://trackmysolutions.us/

Sincerely

Maria Gmitro
Director of Community Outreach & Patient Advocacy
maria.gmitro@trackmysolutions.us
843-501-6873

Jeremy Elias
Founder & CEO
(b)(6)