EXHIBIT B

Napoli Shkolnik Expert Report / Affidavit

prepared by:

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Expert Qualifications

My name is Michael Drues, Ph.D. I am currently an independent regulatory consultant who has worked in the medical device industry for more than 25 years.

I received my B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. I have worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. I also work as a consultant for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

I am an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. I conduct seminars and short courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

I am an Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering and I teach graduate-level courses in Medical Device Regulatory Affairs & Clinical Trials, Combination Products and Pathophysiology at several universities & medical schools including Cornell University Graduate Dept. of Biomedical Engineering and George Washington University Graduate Dept. of Regulatory Science among others.

I am also a contributing editor to several of the largest medical technology and regulatory publications in the world and have a combined readership/listenership averaging 3000+ people per month. For a comprehensive list of my columns, webinar, podcasts, etc., visit, Global Medical Device Podcast (GreenLight.Guru) here, Mike on MedTech (Medical Product Outsourcing) here, Medical Design and Outsourcing here, Guerilla Regulatory Strategy (MED Device Online) here and Healthcare Packaging here or LinkedIn here.

Lastly, over my career I have been involved in designing and testing a wide variety of medical devices from an engineering, medical and regulatory perspective. I am familiar with the variety of medical devices, specifically how they are developed and tested, the regulatory and quality requirements applicable to them as well as the problems associated with them. This includes both medical devices regulated by FDA as well as medical devices not regulated by FDA.

Overview and Introduction

I have been asked by Napoli Shkolnik to render an opinion in the case *Sirls v. City of Flint* on the following question:

> **Question:** Is the product in question, specifically the portable x-ray fluorescence (XRF) system, required to be FDA cleared or approved when used for the detection of environmental lead exposure?
>
> **Answer**:
>
> No, the XRF system does not need FDA clearance or approval when used to detect environmental lead exposure

Overview of US Medical Device Regulation and FDA

Figure 1. US FDA Headquarters, Silver Springs, MD, USA. Taken from here.

Within the United States, the US Food and Drug Administration also known as the FDA (see FDA's homepage here) regulates a wide variety of products in the following areas including:

- Food
- Drugs
- Medical Devices and Radiation-Emitting Products
- Vaccines, Blood, and Biologics
- Animal and Veterinary Products
- Cosmetics
- Tobacco Products

The FDA is organized into various "Centers" based on the type of product(s) regulated. Currently, the list of FDA Centers includes:

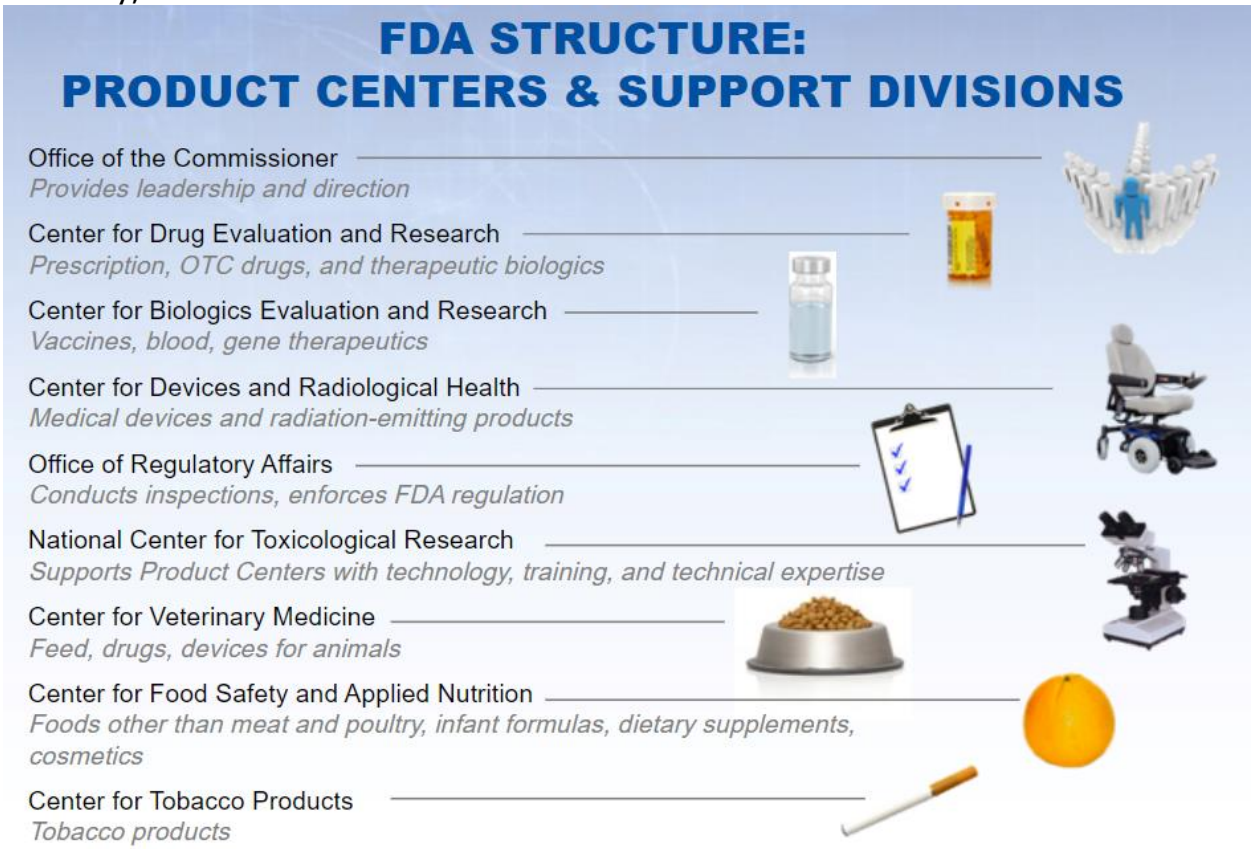

Figure 2. FDA Structure and Product Center Organization. Taken from here.

Specifically, the Center of FDA responsible for regulating medical devices is the Center for Devices and Radiological Health also known as CDRH (see CDRH's homepage here). It is the responsibility of CDRH to regulate all products that fit the Code of Federal Regulations (CFR) definition of a medical device described in the next section here. CDRH's oversight responsibility includes the entire medical device product lifecycle including both pre-market (i.e., design, development, verification and validation testing, etc.) as well as post-market (manufacturing, advertising, post-market surveillance, etc.) activities.

What is a Regulated Medical Device?

The first question a company must ask when beginning the medical device product development process is: ***is the product a regulated medical device?*** To be clear, not all medical devices are regulated by FDA.

If the product is a regulated medical device, then it is/will be subject to FDA regulation. As discussed later in this document, FDA oversees regulated medical devices during both the pre-market and post-market stages of the device's lifecycle.

The FDA considers a product to be a *regulated medical device*, and subject to FDA regulation, if it meets the Code of Federal Regulations (CFR) definition of a medical device. This definition is codified in Section 201(h) of the Food, Drug, and Cosmetic Act as stated (from here):

Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
>
> 1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
> 2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> 3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

The term "device" does not include software functions excluded pursuant to section 520(o).

Based on my nearly 30 years of experience as a professional biomedical engineer and regulatory consultant, the definition of a medical device can be interpreted in many ways. However, the essence of the definition says a regulated medical device is something, other than a drug, that prevents, diagnoses, or treats a disease, injury, or condition.

Medical devices represent a broad spectrum of products from Band-Aids to artificial hearts (see Figure 3). Medical devices are not limited to "physical objects" like heart valves and artificial hips. Medical devices can be liquids, they can be software, i.e., Software as a Medical Device (SaMD) i.e., mobile medical apps, they can be *in vitro* diagnostics (IVDs) i.e., home pregnancy tests, glucose monitors or diagnostics for cancer, to name just a few.

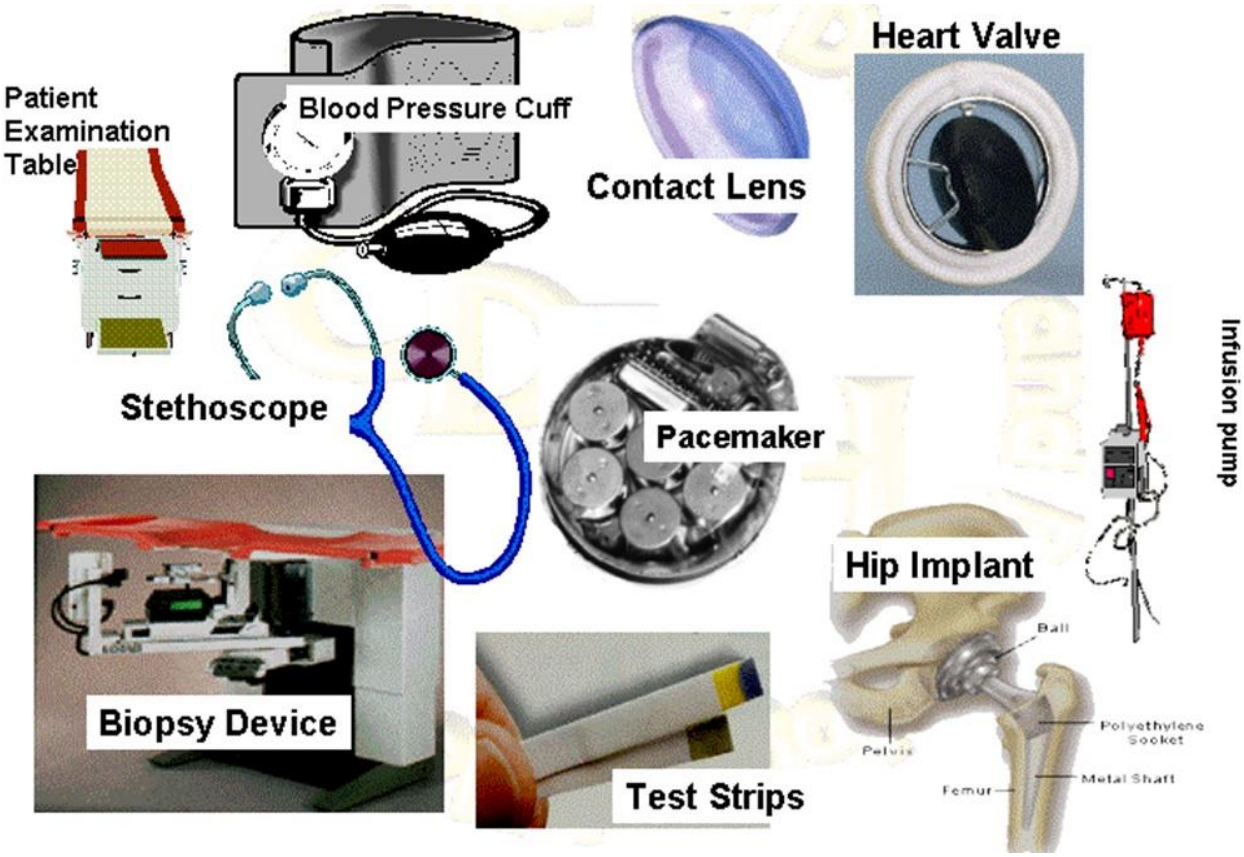

Figure 3. Range of Medical Devices

Medical devices can be invasive (going beneath the skin and/or into the patient's body) or non-invasive (coming in contact with the patient). In some cases, a medical device may not even come in contact with the patient's body at all. In fact, it may not be used in the same room or even in the same building as the patient (i.e., an in vitro diagnostic (IVD) such as pregnancy test, cancer diagnostic, etc.). Finally, medical devices may be used in many "use environments" including in a clinical setting, i.e., hospital or doctor's office, in a tertiary care facility, i.e., a nursing home, in the patient's home, on the battlefield or even in outer space!

Because of the broad nature of the medical device universe, indeed much broader than for drugs or biologics, medical device regulation needs to be broad enough to apply to the entire medical device universe while at the same time specific enough to be actionable by an individual medical device manufacturer and the FDA.

The above applies both *pre-market* during the development of a medical device as well as *post-market* during the marketing and manufacturing of the device. There are two separate and distinct sets of regulations that cover pre-market and post-market activities. However, achieving a balance between broadness and specificity is no easy task.

This is no better demonstrated than in this excerpt from FDA's website describing the Medical Device Quality System Regulation (QSR) here:

> The QS regulation embraces the same "umbrella" approach to the CGMP regulation that was the underpinning of the original CGMP regulation. Because the *regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device* according to the current state-of-the-art manufacturing for that specific device.
>
> *Manufacturers should use good judgment when developing their quality system and apply those sections of the QS regulation that are applicable to their specific products and operations,* 21 CFR 820.5 of the QS regulation. Operating within this flexibility, *it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective,* and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements. *The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated even though the actual work may be delegated.*
>
> FDA has identified in the QS regulation *the essential elements that a quality system shall embody, without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices, production processes, etc., it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement specific procedures tailored to their particular processes and devices.*

As stated on FDA's website above, it is the responsibility of the medical device manufacturer to *interpret* the regulation in order to best apply it to each medical device situation. While some view this "ambiguity" as a challenge, I view it as an advantage!

Summary and Conclusions

After reviewing the information provided, as well as doing some additional regulatory due diligence, the portable x-ray fluorescence (XRF) system would not be subject to FDA regulation for the following reasons:

- **definition:** portable x-ray fluorescence (XRF) does not fit the CFR definition of a medical device as it is not intended to prevent, diagnose, or treat a disease injury or condition

- **precedent:** after searching the appropriate FDA and similar publicly available databases, no other products with similar labeling and/or technology to the portable x-ray fluorescence (XRF) system have found to be regulated by FDA

- **risk:** although the risks associated with the portable x-ray fluorescence (XRF) system are not zero, they are at or below acceptable limits and therefore FDA regulation in the form of safety limits or other special controls are not necessary.
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Therefore, for the reasons stated above, *the portable x-ray fluorescence (XRF) system would not be subject to FDA regulation* and thus no 510k, de novo or PMA would be required.

All opinions described in this document are based on my 25 plus years of experience working in the medical device industry as both a regulatory consultant as well as a professional biomedical engineer. Finally, I reserve my right to change my opinion based on any new or additional information that was not presented to me prior to writing this report.

If you have any questions or require additional information, please do not hesitate to call. Thank you for your consideration.

Respectfully,

Michael Drues, Ph.D.