Microneedles-Based Devices: Regulatory Insights

Kasturi Pawar*

Abstract

Microneedles are classic examples of the fact that the pharmaceutical/medicinal device industry is leading towards a paradigm shift. From past few years, literature and market has been populated with microneedles-based devices claiming a better cosmetic and therapeutic application than existing treatments.

Keywords

Dermaroller; Pacemaker; Cosmeceuticals

Terminologies such as dermaroller and dermastamp have become familiar with general population and increasingly people are choosing such technologies. These treatments are often offered by medical aesthetic facilities, salons and spas and have become quite popular due to the advantages they offer for providing a young-looking, blemish-free, radiant skin. Some of these products are also available and easily accessible through pharmacy stores or online websites such as Amazon, eBay, etc. for use at home.

While it may look very promising and good to use, the question we need to ask is: Are these devices safe? Recent warning letters from FDA for several microneedles-device making companies have raised a serious concern on the safety of these devices that are uninhibitedly being used at home or medical aesthetic facilities/spas/salons [1-5]. Although there is no such clear guidance from FDA yet on microneedles-based devices as of now, FDA has clearly indicated FDA’s Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions. There are various types of medical devices, encompassing from a surgical glove to a pacemaker, and each device is classified per CDRH [6]. The medical device facilities are obliged to review the regulations and identify the appropriate generic device type for their device. Current there are approximately 1,700 different generic types of devices, grouped into 16 medical specialties referred to as panels. Each of these types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. This classification decides the pre-market pathway - exempt (Class I), 510(k) (Class II) or Pre-market approval (PMA) (Class III).

Device classification depends on the intended use of the device (what does the device does) and its indications for use (what does the device treat). This classification system is provided on FDA’s website [7]. Most of the microneedles-device companies register and list their microneedles devices under regulation 21 CFR 878.4820, which is a Class I 510(k) exempt classification with an intended use for general dermabrasion and has been indicated for acne/minor injury-related scar revision, tattoo removal, blemish removal etc. Such devices are considered to be akin to dermabrasion or other similar brushes/tools available in market that does not alter the form and function of the body or skin in this matter in any way. However, some of the products that are available in market, although claim to be Class I, are not actually abiding by the Class I guidelines. These device-making companies are stating false claims on their websites and even claiming a therapeutic activity, which is unlawful. Some even falsely claim terms like: FDA cleared or FDA approved (for sale) based on the fact that their device is FDA-listed or FDA-registered. While it is easy to register the product with FDA or get an FDA-listing, it does not mean the product is FDA-approved for sale or use in US. Registration/listing has nothing to do with the clearance of the device for sale.

FDA ruled that any device with microneedles to be claimed as Class I and get an exempt must have needle length of 0.3 mm or less which assures that the needles are short enough to puncture only the outer (dead) layer of skin and does not go past that layer and affect the structure/function of the skin. In addition, these devices cannot claim any therapeutic benefits. The label, design, functions and marketing has to strictly follow the guidelines for Class I and such devices are exempted from regulation by FDA. Requirements for exempt devices are provided on FDAs website [8]. FDA provides a monthly listings of 510(k)s cleared by FDA [9].

Any microneedles-based device (both manual and motorized) with needles with length exceeding 0.3 mm can alter the form and function of skin and need to be regulated. These include ones that are intended to be used as a delivery system for topical cosmeceuticals or better absorption of pharmaceutical products. Such devices fall under either Class II or Class III. FDA classifies class II device as those for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance. These special controls are usually device-specific and are given on FDA’s website [10]. Devices in this class require submission of a Premarket Notification 510(k), and cannot be commercially distributed until the company receives a letter of substantial equivalence from FDA authorizing for the same. The guidelines for Premarket Notification 510(k) are listed on FDAs website [11].

Devices in Class III are products requiring PMAs as they are considered high risk devices that pose a significant risk of illness or injury, and are found not to be substantially equivalent to Class I and II to predicate through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device. Requirements for Class III devices are listed on FDAs website [12].
Although FDA has gone to great lengths to remove such illegal devices from market and ban their import, it is a difficult task, given these companies once banned, pop up with another name on the website and sometimes selling the product directly to consumer and has no track of supply-chain to confiscate the delivery. Moving forward, it is essential that the consumers recognize the risks associated with such unapproved devices and do not promote these companies by using their products. FDA, given their resources and manpower, are trying their best to ban such products and needs to continue their efforts to make sure that such unapproved products are not sold within the US.

References
9. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/
11. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm
12. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm

Author Affiliations
Department of Formulation and Product Development, Valeant Pharmaceuticals North America, Petaluma, USA