

Characterizing Counterfeit Dermatologic Devices Sold on Popular E-commerce Websites

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PRACTICE POINTS

- Among thousands of counterfeit dermatologic listings, there is great heterogeneity in the number of listings per different subtypes of dermatologic devices, device descriptions, and unit pricing, along with false claims of US Food and Drug Administration clearance.
- Given the prevalence of counterfeit medical devices readily available for purchase online, dermatology practitioners should be wary of the authenticity of any medical device purchased for clinical use.

To the Editor:

Approved medical devices on the market are substantial capital investments for practitioners. E-commerce websites, such as Alibaba.com (<https://www.alibaba.com/>) and DHgate.com (<https://www.dhgate.com/>), sell sham medical devices at a fraction of the cost of authentic products, with sellers often echoing the same treatment claims as legitimate devices that have been cleared by the US Food and Drug Administration (FDA).

In dermatology, devices claiming to perform cryolipolysis, laser skin resurfacing, radiofrequency skin tightening, and more exist on e-commerce websites. These counterfeit medical devices might differ from legitimate devices in ways that affect patient safety and treatment efficacy.^{1,2} The degree of difference between counterfeit and legitimate devices remains unknown, and potential harm from so-called knockoff devices needs to be critically examined by providers.

In this exploratory study, we characterize counterfeit listings of devices commonly used in dermatology. Using the trademark name of devices as the key terms,

we searched Alibaba.com and DHgate.com for listings of counterfeit products. We recorded the total number of listings; the listing name, catalog number, and unit price; and claims of FDA certification. Characteristics of counterfeit listings were summarized using standard descriptive statistics in Microsoft Excel. Continuous variables were summarized with means and ranges.

Six medical devices that had been cleared by the FDA between 2002 and 2012 for use in dermatology were explored, including systems for picosecond and fractionated lasers, monopolar and bipolar radiofrequency skin tightening, cryolipolysis, and nonablative radiofrequency skin resurfacing. Our search of these 6 representative dermatologic devices revealed 47,055 counterfeit product listings on Alibaba.com and DHgate.com. Upon searching these popular e-commerce websites using the device name as the search term, the number of listings varied considerably between the 2 e-commerce websites for the same device and from device to device on the same e-commerce website. On Alibaba.com, the greatest number of listings resulted for picosecond laser (23,622 listings), fractionated laser (15,269), and radiofrequency skin tightening devices (3555); cryolipolysis and nonablative radiofrequency resurfacing devices had notably fewer listings (35 and 38, respectively). On DHGate.com, a similar trend was noted with the most numerous listings for picosecond and fractionated laser systems (2429 and 1345, respectively).

Among the first 10 listings of products on Alibaba.com and DHgate.com for these 6 devices, 10.7% (11 of 103) had advertised claims of FDA clearance on the listing page. Of 103 counterfeit products, China was the country of origin for 100; South Korea for 2; and Thailand for 1. Unit pricing was heterogeneous between the 2 e-commerce websites for

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the counterfeit listings; pricing for duplicate fractionated laser systems was particularly dissimilar, with an average price on Alibab.com of US \$8105.80 and an average price on DHgate.com of US \$3409.14. Even on the same e-commerce website, the range of unit pricing differed greatly for dermatologic devices. For example, among the first 10 listings on Alibaba.com for a fractionated laser system, the price ranged from US \$2300 to US \$32,000.

Counterfeit medical devices are on the rise in dermatology.^{1,3} Although devices such as radiofrequency and laser systems had thousands of knockoff listings on 2 e-commerce websites, other devices, such as cryolipolysis and body contouring systems, had fewer listings, suggesting heterogeneity in the prevalence of different counterfeit dermatologic devices on the market.

The varied pricing of the top 10 listings for each product and spurious claims of FDA clearance for some listings highlight the lack of regulatory authority over consistent product information on e-commerce websites. Furthermore, differences between characteristics of counterfeit device listings can impede efforts to trace suppliers and increase the opacity of counterfeit purchasing.

Three criteria have been proposed for a device to be considered counterfeit³:

- *The device has no proven safety or efficacy among consumers.* For example, the substantial threat of copycat devices in dermatology has been demonstrated by reports of burns caused by fake cryolipolysis devices.²

- *The device violates patent rights or copy trademarks.* Due to the regional nature of intellectual property rights, country-specific filings of patents and trademarks are required if protections are sought internationally. In this study, counterfeit devices originated in China, South Korea, and Thailand, where patent and trademark protections for the original devices do not extend.

- *The device is falsely claimed to have been cleared by the FDA or other clinical regulatory authorities.* Legitimate medical devices are subject to rounds of safety and compatibility testing using standards set by regulatory bodies, such as the FDA's Center for Devices and Radiological Health, the International Organization of Standardization, and the

International Electrotechnical Commission. Compliance with these safety standards is lost, however, among unregulated internet sales of medical devices. Our search revealed that 10.7% of the top 10 counterfeit device listings for each product explicitly mentioned FDA clearance in the product description. Among the thousands of listings on e-commerce sites, even a fraction that make spurious FDA-clearance claims can mislead consumers.

The issue of counterfeit medical devices has not gone unrecognized globally. In 2013, the World Health Organization created the Global Surveillance and Monitoring System to unify international efforts for reporting substandard, unlicensed, or falsified medical products.⁴ Although universal monitoring systems can improve detection of counterfeit products, we highlight the alarming continuing ease of purchasing counterfeit dermatologic devices through e-commerce websites. Due to the widespread nature of counterfeiting across all domains of medicine, the onus of curbing counterfeit dermatologic devices might be on dermatology providers to recognize and report such occurrences.

This exploration of counterfeit dermatologic devices revealed a lack of consistency throughout product listings on 2 popular e-commerce websites, Alibaba.com and DHgate.com. Given the alarming availability of these devices on the internet, practitioners should approach the purchase of any device with concern about counterfeiting. Future avenues of study might explore the prevalence of counterfeit devices used in dermatology practices and offer insight on regulation and consumer safety efforts.

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