# Guidance for Industry and FDA Staff

# Frequently Asked Questions (FAQs) on the Status of Reprocessed Single Use Devices (SUDs) that receive a Not Substantially Equivalent (NSE) Letter

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**U.S. Department of Health and Human Services**
**Food and Drug Administration**

**Center for Devices and Radiological Health**

# Preface

## Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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# Frequently Asked Questions (FAQs) on the Status of Reprocessed Single Use Devices (SUDs) that receive a Not Substantially Equivalent (NSE) Letter



## 1. What is a Not Substantially Equivalent letter and what does it mean if it pertains to a reprocessed SUD?

In general, firms submit premarket information to FDA for the purpose of obtaining marketing approval or clearance of their devices prior to commercial distribution. A premarket approval application (PMA) is usually required for entirely new types of devices, while a premarket notification submission (510(k)) may be submitted to demonstrate that a device is "substantially equivalent" to a legally marketed device (a "predicate" device) that did not require a PMA.

If FDA agrees that a device for which a 510(k) has been submitted is substantially equivalent to a legally marketed device, FDA issues a Substantially Equivalent (SE) letter. A "Not Substantially Equivalent" (NSE) letter is issued when FDA, based on the information submitted, determines that the device is not substantially equivalent to the already legally marketed device. Like any other 510(k) applicant, a SUD reprocessor who submits a 510(k) and receives an NSE letter may not legally market the device subject to that 510(k) because it has not been cleared for commercial distribution by FDA.

Some firms who previously received SE letters for certain reprocessed SUDs were required, by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), to submit additional cleaning, sterility, and functionality validation data (supplemental data) for FDA to review in order to determine if these reprocessed devices could continue to be legally marketed. If these firms either failed to submit the required supplemental data or FDA determined, based on the supplemental data submitted, that the reprocessed devices were not substantially equivalent to legally marketed predicate devices, the firms received NSE letters from FDA. If a firm submitted supplemental data to FDA but later withdrew its 510(k)s as described in section 302(b) of MDUFMA, it received a letter acknowledging the withdrawal from FDA.

Upon receipt of a NSE letter or a letter acknowledging withdrawal, the device subject to the letter may no longer be legally marketed. The reprocessor may notify its customers that it can no longer reprocess that device at this time. However, a reprocessor may submit a new 510(k) that includes the validation data required under MDUFMA and may be able to resume marketing if and when FDA determines that the information in the new 510(k) is adequate to establish substantial equivalence and issues a SE letter.

## 2. Will FDA require reprocessors to recall a distributed device that is the subject of a NSE letter or a letter acknowledging withdrawal?

Not necessarily. FDA intends to contact each affected reprocessor to determine their plans for retrieval or withdrawal of distributed product. In accordance with 21 CFR Part 7 and section 518(e) of the Federal Food, Drug, and Cosmetic Act (the Act), FDA will evaluate, on a case by case basis, whether the device that is the subject of the NSE or withdrawal letter should be recalled.

## 3. Should a customer continue to use in-stock, reprocessed SUDs once the reprocessor can no longer distribute as a result of a NSE letter or a letter acknowledging withdrawal?

Upon receipt of a NSE letter or a letter acknowledging withdrawal, the device subject to the letter may no longer be legally marketed. Customers may wish to contact the reprocessor to learn about any plans for retrieval or withdrawal of in-stock devices. If the device warrants a recall, the recall strategy will specify the level to which the recall will extend, as described in 21 CFR Part 7 or section 518(e) of the Act.

## 4. Is there an FDA site that lists information about which reprocessed SUDs are no longer eligible for commercial distribution?

Reprocessors who received 510(k) clearances prior to the requirement under the law to submit supplemental data, have those 510(k)s posted on FDA's searchable 510(k) database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Most SUD reprocessors who were required to submit supplemental data under MDUFMA, did submit. If FDA determined, based on a review of the supplemental data, that a device is Not Substantially Equivalent or if the SUD reprocessor requested withdrawal of the 510(k) and

supplemental data submission, the original 510(k) Substantial Equivalence determination was removed from the FDA's 510(k) database. In addition, a list of the devices that can no longer be legally marketed is provided separately on FDA's reuse website at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm20081513.htm.

## 5. What other information can I learn from the FDA's website about the status of reprocessed SUDs that were subject to supplemental data requirements?

In addition to identifying reprocessed devices that can no longer be legally marketed, the site also lists those reprocessed devices for which FDA reviewed supplemental data submissions and determined that these devices remain substantially equivalent to legally marketed predicate devices. MDUFMA did not require the submission of supplemental data for all reprocessed SUDs, however, so these lists will not provide a complete accounting of all reprocessed SUDs. For additional information on the reprocessed devices for which supplemental data were required by MDUFMA, see List I and II published in the Federal Register on June 26, 2003 (http://www.fda.gov/OHRMS/DOCKETS/98fr/03-16109.html, 68 FR 38071.

## 6. If I have additional questions, who can I contact?

FDA recommends that you first contact the SUD reprocessor for information about the device in question. You may also contact the 510(k) Staff within the Office of Device Evaluation, CDRH at (301) 594-1190 or the Office of Compliance, CDRH at (240) 276-0100.