Important Information Regarding Listing Requirements for Medical Device Data Systems

CDRH Registration and Listing <reglist@cdrh.fda.gov>
To: "jcortell@kanteron.com" <jcortell@kanteron.com>

Wed, Oct 5, 2016 at 9:16 PM

Dear Jorge Cortell-Albert;

On February 9, 2015, FDA issued a final Guidance for Industry and Food and Drug Administration Staff to inform manufacturers, distributors, and other entities that the Agency does not intend to enforce compliance with the regulatory controls that apply to MDDS, medical image storage devices, and medical image communications devices, due to the low risk they pose to patients and the importance they play in advancing digital health.

Medical device establishment registration and listing are among the regulatory controls that the agency does not intend to enforce for MDDS, medical image storage devices, and medical image communications devices. The product codes below, therefore, do not require registration and listing at this time:

Product Code	Device Regulation	Device Generic or Common Name
LMB	21 CFR 892.2010	DEVICE, DIGITAL IMAGE STORAGE, RADIOLOGICAL
LMD	21 CFR 892.2020	SYSTEM, DIGITAL IMAGE COMMUNICATIONS, RADIOLOGICAL
NFF	21 CFR 892.2010	DEVICE, STORAGE, IMAGES, OPHTHALMIC
NFG	21 CFR 892.2020	DEVICE, COMMUNICATIONS, IMAGES, OPHTHALMIC
OUG	21 CFR 880.6310	MEDICAL DEVICE DATA SYSTEM
NXQ	21 CFR 890.5050	DAILY ASSIST DEVICES

A review of those establishments registered and devices listed in the FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM) during Fiscal Year 2016 shows that your company has listed one or more medical devices under these product codes with FDA as shown below.

Establishment Name: KANTERON SYSTEMS, S.L.U.
Registration Number: 3010408861
Owner/Operator Number: 10044162
Listings:

- D194733; Product Code: LMD

Please be aware that listing is not required for these products and that FDA will be updating our product code database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm) to reflect that registration and listing is not required for these product codes.

You may update or deactivate your listings for these products at any time by signing into FURLS DRLM (https://www.access.fda.gov/oaa) and choosing "Change, Deactivate, or Reactivate Listings." Please be aware that you are required to update your registration and listings - by either re-registering or deactivating your registration - for Fiscal Year 2017 during the period beginning October 1, 2016 and ending December 31, 2016.

If you have any questions or need assistance with using FURLS DRLM, please contact us at reglist@cdrh.fda.gov or 301-796-7400, Option 1.

Sincerely,

David Gartner
Team Leader,
CDRH Registration and Listing Program

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