

LSIdaho Inc.
Voice: (208) 429-9895
FAX: (208) 429-9762

FDA Questionnaire on medical devices

Fax to: _____

Description of product, including use. Advise if this is sterile or non-sterile.

Provide FDA product code from the FDA web page.

Please provide the actual manufacture name, and address, if NOT the shipper shown on the importation documents.

Please provide the following affirmation of compliance numbers for FDA:

Importers owner/operator number: _____ **(DEV)**
(7 digit numerical)

Device registration number: _____ **(DEV)**
(A,B,Q and 6 digits)

Device listing number: _____ **(LST)**
(Manufacturers list 6 –7 digits)

Device pre-market approval number OR pre-market notification number (510K)
(your product may not be subject to this identifier)(K plus 6 digits)

For laser or infrared items – please provide accession number and 2877 form

The best source of information regarding importations subject to compliance with FDA is on the FDA web site. Access it at FDA.GOV
You may also contact FDA at 800-991-4881