FamilyTreeDNA | Tax ID (EIN): 76-0640295
1445 North Loop West, Suite 820, Houston, TX 77008
+1 832-968-8132 | shipments@genebygene.com (kit number required)

FDA Exemption Documentation

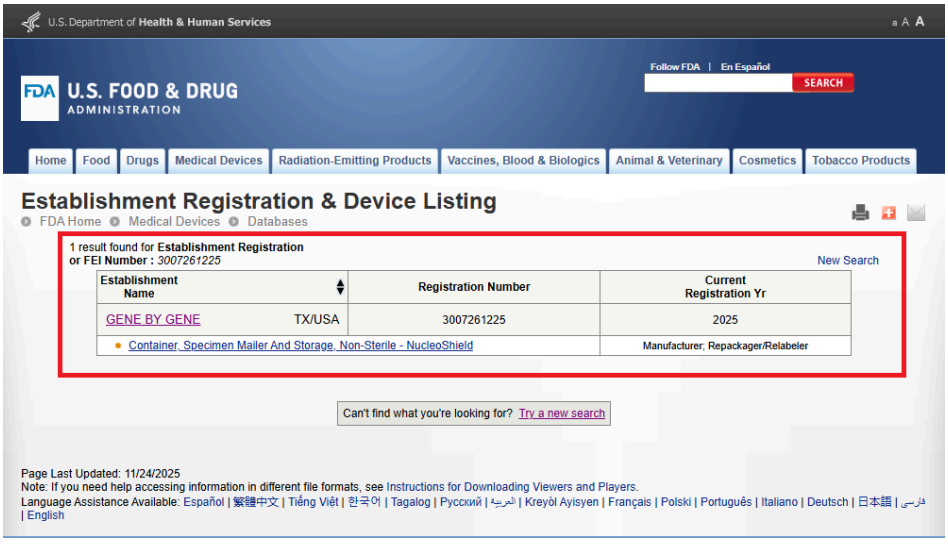
Returns to the United States for Processing - NOT for MEDICAL or DIAGNOSTIC PURPOSES

Collection Kit FDA Exempt - Class I (21 CFR 864.3250)
FDA Reg. No. 3007261225

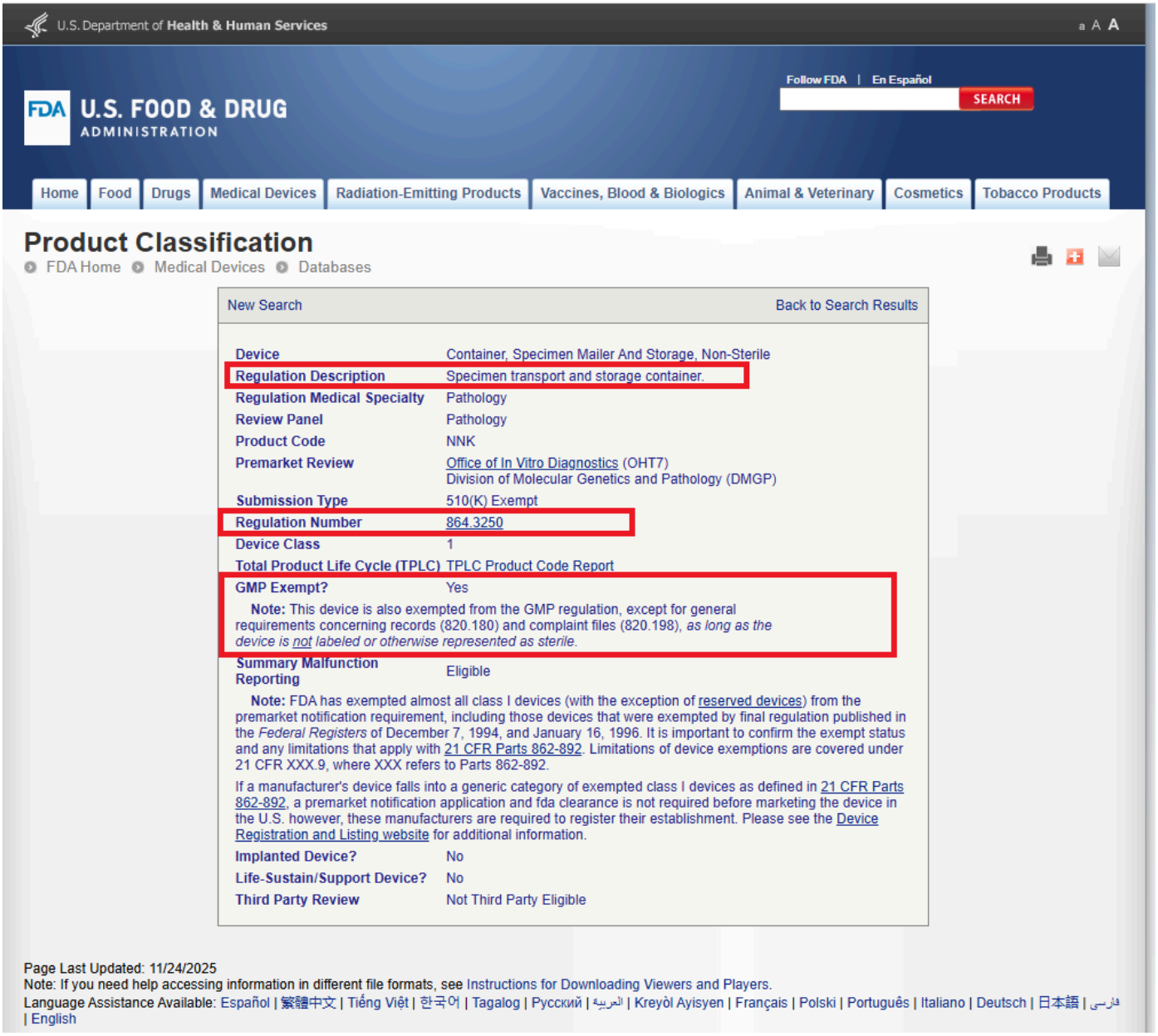
FDA Establishment Registration Number	3007261225 (GENE BY GENE, 1445 N Loop Suite 820, Houston, TX 77008)
Registered Establishment Operations	Manufacturer; Repackager/Relabeler
Proprietary Name	NucleoShield
Classification Name	Container, Specimen Mailer and Storage
Product Code / Device Class	NNK / 1
Applies To	Collection kit with vials
Regulation Number	864.3250 (Specimen transport and storage container)
Submission Type	510(K) Exempt
Owner/Operator	Gene By Gene, Owner/Operator Number 10090751
Why exempt	FDA classifies a specimen transport and storage container as Class I (general controls) and exempts it from premarket notification (510(k)), subject to 21 CFR 864.9.
Governing regulations	21 CFR 864.3250 (classification and exemption); 21 CFR Part 807 (registration and listing)
Specimen	The exemption covers the collection kit, not the specimen (human material imported for laboratory ancestry testing).
Purpose/Use	The contents are returned to the United States for ancestry research (non-medical, non-diagnostic) processing.

The FDA listing pages are shown below and on pages 2 and 3 (FDA pages last updated 11/24/2025).

FDA listing page 1 of 3. Establishment Registration Search Result: GENE BY GENE, Registration Number 3007261225



FDA listing page 2 of 3. Product Classification: Product Code NNK, Class 1, Regulation 864.3250, 510(K) Exempt



U.S. Department of Health & Human Services

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Device	Container, Specimen Mailer And Storage, Non-Sterile
Regulation Description	Specimen transport and storage container.
Regulation Medical Specialty	Pathology
Review Panel	Pathology
Product Code	NNK
Premarket Review	Office of In Vitro Diagnostics (OHT7) Division of Molecular Genetics and Pathology (DMGP)
Submission Type	510(K) Exempt
Regulation Number	864.3250
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes

Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), *as long as the device is not labeled or otherwise represented as sterile.*

Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Page Last Updated: 11/24/2025

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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FDA listing page 3 of 3 (a). Establishment Registration & Device Listing: GENE BY GENE (Registration Number 3007261225)

