## DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

**DEVICE LISTING** 

Form Approved: OMB No. 0910-0387. Expiration Date: December 31, 2001.

Complete and Return to: Food and Drug Administration Center for Devices and Radiological Health Information Processing and Office Automation Branch (HFZ-308) 9200 Corporate Blvd. Rockville, MD 20850-4015 This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001. DOCUMENT NUMBER 2. REASON FOR SUBMISSION 3. REPORT DATE 4. OWNER / OPERATOR ID NUMBER -DAY X New Listing 018736 Update to Device Already Listed 9026669 Delete Listing OWNER / OPERATOR NAME Sierra Diagnostics, LLC ADDRESS (Check if same as submitted on FDA Form 2891) a. NUMBER and STREET 21109 Longeway Road, #C b. CITY, STATE, ZIP CODE c. FOREIGN COUNTRY Sonora, CA 95370 7. CLASSIFICATION NAME 8. CLASSIFICATION NUMBER Microbiological Specimen Collection JTW and Transport System 9. PROPRIETARY NAME (Brand Name) Multiple COMMON OR USUAL NAME Urine Collection add Transport System 11 FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS a. NAME b. REGISTRATION NUMBER ESTABLISHMENT NAME AND ADDRESS (Identification of Sites Where Listed Device is Produced) (Name, Street Number, City, State or Country, ZIP or Postal Code) REGISTRATION NO. **ESTABLISHMENT TYPE** 2953142 Sierra Diagnostics, LLC M 21109 Longeway Road, #C X Sonora, CA 95370

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other ect of this collection of information, including suggestions for reducing this burden to:

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An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

13. SIGNATURE

14. TYPED OR PRINTED NAME

Tony K. Baker