DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Immuno Concepts N.A., Ltd. June 17, 2016
Eric S. Hoy, Ph.D.
Chief Scientific Officer
9825 Goethe Road, Suite #350
Sacramento, CA 95827

Re: K160265
Trade/Device Name: HEp-2000® Fluorescent ANA/Ro Test System;
Image Navigator by Immuno Concepts
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: DHN, PIV
Dated: May 7, 2016
Received: May 16, 2016

Dear Dr. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kelly Oliner -S

For,
Leonthena R. Carrington, MS, MBA, MT (ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160265

Device Name
HEp-2000® Fluorescent ANA-Ro Test System
Image Navigator by Immuno Concepts

Indications for Use *(Describe)*
Instrument
The Immuno Concepts Image Navigator is an automated system consisting of a fluorescent microscope and software that acquires, interprets, stores, and displays digital images of stained indirect immunofluorescent slides. The Image Navigator can only be used with cleared or approved Immuno Concepts in vitro diagnostic assays that are indicated for use on the microscope. All suggested results generated by the Image Navigator software must be confirmed by trained laboratory personnel.

Assay
This is an indirect fluorescent antibody test for the semi-quantitative detection of IgG antinuclear antibody (ANA) in human serum by manual fluorescent microscopy or with the Image Navigator Fluorescence Semi-Automated Microscope. This test system uses transfected† HEp-2000® cells, which allow specific identification of autoantibodies to the SSA/Ro antigen. Autoantibodies to SSA/Ro may show a distinctive staining pattern on the transfected cells. When this pattern is present, it is considered to be confirmatory evidence that anti-SSA/Ro antibodies are present.

Absence of this distinctive pattern does not rule out the possible presence of anti-SSA/Ro antibodies.

This test system is to be used as an aid in the detection of antibodies associated with systemic rheumatic disease in conjunction with other laboratory and clinical findings. A trained operator must confirm results generated with the Image Navigator semi-automated device and software.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.