DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 10, 2014

H.S. Hospital Services S.p.A.
Mr. Lucio Improta
General Manager
Via A. Vacchi, 24/26
04011 Aprilia LT, ITALY

Re: K131925
Trade/Device Name: HS NOTA
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG
Dated: September 25, 2014
Received: September 29, 2014

Dear Mr. Improta:

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 Part 801); 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" (21 CFR 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 yours,

Binita S. Ashar -S
2014.10.10 13:08:15 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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)*
K131925

Device Name
HS NOTA

Indications for Use *(Describe)*
HS NOTA is an automatic biopsy needle and can be used in Fluoroscopic, CT and Mammographic procedures to obtain biopsies of soft tissue including those from prostate, kidney, breast and liver.
The device is for prescription use, to be used by physicians in hospitals and clinics.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K131925

5. 510(k) Summary

1. Submitter Information

Owner: H.S. Hospital Service S.p.A.
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Date summary prepared: October, 07 2014

2. Name of Device

Trade or Proprietary Name: **HS NOTA**

Common or Usual Name: Biopsy needle

Regulation Name: Gastroenterology-urology biopsy instrument
Product code: FCG
Regulation number: 876.1075
Class: II

3. Predicate device:

The HS Nota is substantially equivalent to the following legally marketed device:

- HS Hospital Service S.p.A. "PRECISA" biopsy needle cleared and marketed under K002944.

4. Intended use

HS NOTA is an automatic biopsy needle and can be used in Fluoroscopic, CT and Mammographic procedures to obtain biopsies of soft tissue including those from prostate, kidney, breast and liver. The device is for prescription use, to be used by physicians in hospitals and clinics.

Equivalently, the predicate device is an automated disposable and adjustable biopsy needle to be used in fluoroscopic CT and mammographic procedures to obtain biopsies of various tissues including those from prostate, kidney, breast and liver (soft tissues).
Also, the predicate device is for prescription use, to be used by physicians in hospitals and clinics

5. Functioning

Both HS NOTA and the predicate device are based on the TRU-CUT methodology (also known as modified Vim-Silverman technique) to obtain biopsies of soft tissues.

6. Device description

Both the HS NOTA and the predicate device consist of a 304 stainless steel cannula and stylet. In both the devices the cannula and stylet inner handles are moved by springs that must be loaded, toward a charging lever positioned on the external housing of the needle, before firing the needle.
Both PRECISA and HS NOTA are single patient use, disposable, sterile and non-pyrogenic products.

The external plastic handle of HS NOTA has a different shape relative to the predicate device. This difference does not affect the performance or safety of the device as it does not affect the advancement and penetration of the needle inside the tissues, yet it just implies a different way for the user to handle the device.

The charging lever for PRECISA needle is straight, it means operator must pull-it for charging, while the NOTA one is designed to be rotated for loading the springs. This difference is a consequence of the specific external plastic handles of HS NOTA relative to the predicate device and does not impact in safety and effectiveness of the needles.

HS NOTA needle performs a biopsy of 2.5 cm of length inside the soft tissue. PRECISA needle can be adjusted to advance 1 cm or 2 cm of length. When considering PRECISA needle in 2 cm advancing configuration there is a total equivalence between the two devices. Indeed the additional run of 0.5 cm characterizing HS NOTA, is only due to the different inner mechanism of the HS NOTA compared to PRECISA and it does not affect safety and effectiveness: final outcomes in terms of quality and length of the bioptic samples depend on the notch realized on the stylet (shape of stylet tip) which is exactly the same for both HS NOTA and PRECISA.

The sample notch size is 20 mm. So maximum length for core collected is 20 mm.

The shape of cannula and stylet tips are exactly the same for HS NOTA and PRECISA. It means that the HS NOTA and PRECISA are substantially equivalent as capacity to cut the soft tissue.

The Spring used inside the two devices are exactly the same, it means that the force moving the cannula and stylet of both the needle is exactly the same.

Needles diameter characterizing both HS NOTA and PRECISA are 14G, 16G, 18G, and 20G. Furthermore both the devices are provided with needles characterizing by a length within the range 7 cm-25 cm.

HS NOTA is provided with a safety element that is automatically activated as the spring has been loaded. The safety feature must be removed by the physician to fire the device. This mechanism allows to avoid accidental firing of the needle. The predicate device has been manufactured with an identical safety element.

Inner mechanism: The inner mechanism for an automatic biopsy device is responsible for the automatic movements of both stylet and cannula composing the needle. The inner mechanism of HS NOTA is composed by:

1. 2 plastic handles, each plastic handle is attached to stylet and cannula distal part, both these handles slide inside the external plastic housing of the product, each plastic handle is provided with hooking means capable to retain the handle in charged position once the spring has been charged
2. Inner spring that must charged, they are responsible for the automatic advancing of the inner plastic handles.
3. A firing lever which is capable to pull back the inner plastic handles (loading the spring) during the charging phase and which is capable to act on the hooking means (which are part of the inner plastic handles) realising them and making possible the inner handles advancing.

PRECISA inner mechanism is composed by the same functional elements.
During the functioning of the product no mechanical damages on these parts must occur.

Materials:
The only part of HS NOTA coming in contact with the patient is represented by the cannula and stylet that are made of biocompatible AISI 304 material, identically to the predicate device. The external part of the device representing the plastic handle is made of nylon while PRECISA's plastic handle is made of ABS. This difference does not affect effectiveness and safety of the device since both nylon and ABS have equivalent characteristics: they are thermoplastic materials allowing the needle to move properly and providing adequate resistance to the force exerted by the spring on the device.

Performance test
HS NOTA was tested according to the Guidance for the Content of Premarket Notifications for Biopsy Device used in gastroenterology and urology (Section XI).
Especially two identical tests were performed considering different samples:
1) The first test was performed on bovine liver (loose and a low density tissue) and bovine scrotum (very fibrotic and a high density tissue) representing the worst cases conditions.

The results of the test demonstrate good needle advancement and penetration and give evidence that the device is capable of being fired and is able to obtain the claimed (20) amount of samples without damage to the interior mechanism, and that the quality and size of the biopsy sample taken with the later shots are equivalent for the type of tissues for which the device is indicated.
This kind of test represents a HS HOSPITAL SERVICE standard for all the marketed automatic biopsy needles. It means that the same functional test was performed on the "PRECISA" needle and gave equivalent results.
2) The second test was performed considering pork lard and bovine fat as they have intermediate characteristics compared to the boundary conditions considered in test 1, in term of consistence, density and hardness that are the characteristics affecting the performance of the device. Overall the results obtained with this second test confirm good needle advancement and penetration with no damages to the interior mechanism nor in the cores and again, the devise was able to obtain the claimed (20) amount of samples. Also, the core length obtained using the fat samples are in line with those obtained when HS NOTA performance was tested on the bovine liver and scrotum (test 1). Specifically the averaged core length of biopsies from fat samples gave values that are higher than the values obtained on the bovine scrotum (a more fibrotic and denser tissue) but lower that those measured on the bovine liver (characterized by poor consistence and density).
Therefore, the fat samples fall within the range of the identified boundary conditions (scrotum and liver tissues) further corroborating the effectiveness and safety of the subject device.

In conclusion the performance tests demonstrate that the HS NOTA devise is as safe, as effective, and performs at least as well as the legally marketed predicate device HS PRECISA.