DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 31, 2016

Novatech S.A.
% Mr. Stuart Montgomery
Boston Medical Products Incorporated
117 Flanders Road
Westborough, Massachusetts 01581

Re: K151832
Trade/Device Name: Novatech® Talcair™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 2, 2016
Received: March 7, 2016

Dear Mr. Montgomery:

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,

Jennifer R. Stevenson -A

For 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)*
K151832

Device Name
NOVATECH® TALCAIR

Indications for Use *(Describe)*
Treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural fluid.

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.

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510(K) SUMMARY

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Date Prepared

March 26, 2015

II. DEVICE

Trade Name:	NOVATECH® TALCAIR™
Common Name:	Powder Blower
Device Classification Name:	Laparoscope, General & Plastic Surgery
Regulation Number and Description:	876.1500 Endoscope and accessories
Review Panel:	General & Plastic Surgery
Product Code:	GCJ
Device Class:	2

III. PREDICATE DEVICE

Device Name: KARL STORZ ENDOSCOPY POWDER BLOWER
Original Applicant: KARL STORZ ENDOSCOPY-AMERICA, INC.
510(k) Number: K952443
Product Code/Regulation Number: GCJ/876.1500 Endoscope and Accessories

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

NOVATECH® TALCAIR™ is a powder blower comprised of an insufflation cannula, an insufflation bulb and its connecting pieces (a coupling, and a luer connector). The coupling, which is made of polypropylene, is used to attach the device to a vial.

The device is a sterile, single use medical device which is sterilized by gamma sterilization.

The coupling will be inserted into the glass vial. The cannula, made of polyethylene, is attached to the exit of the coupling. The insufflation bulb has two valves and a tube. The bulb and the tube are made of Soft-PVC. The luer connector, made of radiation grade polycarbonate, is attached to the tube of the insufflation bulb. The luer connector is to be attached to the coupling. When ready for use, the coupling is to be firmly pressed onto the vial until the coupling "clicks" on the vial top. Attach the balloon to the coupling with the luer connector. For administration, the cannula is introduced into the body cavity and pulverization is started.

The medical device is intended for the administration of medical grade talc via thoracoscopy. The device is intended to treat patients with malignant pleural effusion.

V. INDICATION FOR USE

Treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural fluid.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The NOVATECH® TALCAIR™ has the same indication for use, uses the same operating principle and incorporates the same basic design as the predicate device, the KARL STORZ ENDOSCOPY POWDER BLOWER. A summary of the technological characteristics of NOVATECH® TALCAIR™ compared to KARL STORZ ENDOSCOPY POWDER BLOWER is provided below.

Tabular Comparison to Predicate Device

Item	Proposed Device: NOVATECH® TALCAIR™	Predicate Device: KARL STORZ ENDOSCOPY POWDER BLOWER
Product Code	GCJ	Same
Regulation Number	876.1500	Same
Class	2	Same
Intended Use	Administration of medical grade talc via thoracoscopy. The device is intended to treat patients with malignant pleural effusion.	Same
Indication for Use	Treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural fluid.	Same
Patient Population	Those diagnosed with malignant pleural effusion.	Same

Anatomical Sites	Introduced into the pleural cavity.	Same
Environmental of Use	Hospital	Same
Energy used and / or delivered	Air insufflation occurs by the manually operated rubber bulb.	Same
Principal Operator	Physicians with experience in thoracoscopy in cooperation with trained staff	Same
Design	Powder Blower comprising an insufflation cannula with an attached vial coupling, and a separate insufflation bulb. The semi-rigid insufflation cannula has an effective length of about 16.5 inches (42 cm) at an outer diameter of 0.102 inches (3 mm). The attached vial coupling is used to snap-fit the vial. The separate insufflation bulb has two valves controlling the one-way direction of airflow. Insufflation bulb and vial coupling are connected by luer connectors before device use.	Powder Blower comprising a glass bottle, an insufflation cannula, and an insufflation bulb. The rigid insufflation cannula has a length of about 16.5 inches (42 cm) at an outer diameter of 0.2 inches (5 mm). The attached vial coupling is used to screw the device to a vial. The separate insufflation bulb has two valves controlling the one-way direction of airflow. Insufflation bulb and vial coupling are connected by an additional tube segment featuring luer connectors before device use.
Materials	PVC, Polyethylene, Polycarbonate	PVC, Stainless Steel
Principles of Operation	The NOVATECH® TALCAIR™ vial coupling is inserted into the vial by pressing the vial coupling onto the vial. The insufflation bulb is then attached to the vial coupling.	Same
Sterilization	NOVATECH® TALCAIR™ is a single use product and is supplied sterile. Instructions for sterilization and re-sterilization/re-use of the product are unnecessary. Therefore, effectiveness of any kind of reuse and reprocessing has not been demonstrated.	Cleaning and sterilization instructions are supplied by STORZ which recommends a steam sterilization at 134°C, for 5 minutes.
Sterility	NOVATECH® TALCAIR™ is supplied sterile and is intended	Delivered un-sterile

	for single use according to the sterilization validation of the product.	
Shelf Life	5 years	unknown

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The assessment of biological risks, the procedures and provisions of EN ISO 10993-1:2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process2 (including Technical Corrigendum 1, published on 15 June 2010), as well as Blue Book Memorandum G 95-1 / FDA Draft Guidance dated April 23, 2013 "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" were applied.
NOVATECH® TALCAIR™ is biological classified "external communicating device" with "limited" (<24 h) contact to "tissue, bone or dentin".

In accordance with the aforementioned standards and regulatory documents the following biological risks were particularly evaluated:

- Cytotoxicity EN ISO 10993-5:2009
- Irritation EN ISO 10993-10:2010
- Delayed type hypersensitivity EN ISO 10993-10:2010
- Acute systemic toxicity EN ISO 10993:11:2009
- Chemical characterization EN ISO 10993-18:2009

For sample preparation and dosing EN ISO 10993-12:2012 is applicable.

All other risks mentioned in EN ISO 10993-1, including serious risks like systemic toxicity (subchronic, chronic), implantation, genotoxicity, hemocompatibility, carcinogenicity, reproductive and developmental toxicity, biodegradation, toxicokinetics and immunotoxicity are deemed not relevant, respectively not applicable.

Benchmark Performance Tests

This 510(k) includes a test report for benchmark performance tests on NOVATECH® TALCAIR™. The purpose of this evaluation was to demonstrate the technical equivalence of the NOVATECH® TALCAIR™ powder blower with the KARL STORZ ENDOSCOPY POWDER BLOWER. The following were tested for both devices:

- Ejection volume in relation to flow
- Distribution pattern of sprayed talc
- Pressure and volume changes

The results show that NOVATECH® TALCAIR™ has an equal or better performance for talc distribution, spray coverage patter, pressure safety and yield of dosage against the KARL STORZ ENDOSCOPY POWDER BLOWER.

VIII. SHELF LIFE / STERILIZATION

Transport Validation

A sterile barrier test after distribution transport simulation was performed on NOVATECH® A sterile barrier test after distribution transport simulation was performed on NOVATECH® TALCAIR™. The purpose of this evaluation is to demonstrate that the sterile barrier of the primary package remains intact using the actual materials, sealing paramaters, secondary packaging, usually shipping boxes and configurations. Seal strength tests according to EN 868-10 and dye penetration tests according to ASTM F1929 have been performed after exposure to simulated transport conditions according to ISTA procedure 2A for international shipping up to a shipping unit weight of 68 kg.

To validate the sterile sealing seam a seal strength tests according to EN 868-10 and a dye penetration leakage test according to ASTM F1929-12 have been performed.

It can be assumed that the product can be provided sterile to the end-user after being exposed to transport situations covered by the ISTA 2A procedure which is representative for shipping units up to 68 kg to worldwide destinations only restricted by extreme climate beyond the simulation parameters.

Shelf Life

The shelf life for NOVATECH® TALCAIR™ is five years. For shelf life tests on NOVATECH® TALCAIR™ two test reports were provided.

Sterilization

***Method of Sterilization*:**	Gamma Radiation
***Sterility Assurance Level*:**	10^{-6}
***Radiation Dose*:**	15 kGy

IX. CONCLUSION

Based on above criteria's, substantial equivalence between NOVATECH® TALCAIR™ and the predicate device - KARL STORZ ENDOSCOPY POWDER BLOWER can be established.

Pursuant to section 21 CFR 807.100 Novatech SA has determined that NOVATECH® TALCAIR™ is substantially equivalent to Predicate device - KARL STORZ ENDOSCOPY POWDER BLOWER through the data and information presented. No safety or effectiveness issues were identified.