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

March 13, 2017

NOVATECH S.A.
% Mr. Stuart K. Montgomery
President
Boston Medical Products Inc.
70 Chestnut Street
Shrewsbury, Massachusetts 01545

Re: K170030
Trade/Device Name: NOVATECH TALCAIR
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 2, 2017
Received: January 4, 2017

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,

Jennifer R. Stevenson -S

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)*
K170030

Device Name
NOVATECH® TALCAIR™

Indications for Use *(Describe)*
The device is intended for manual insufflation of medical grade talc into the pleural cavity during pleurodesis. The device is indicated for use according to the approved indication for use of the medical grade talc.

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

January 2, 2017

2 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

3 Predicate Device

Device Name:	NOVATECH® TALCAIR™
Original Applicant:	Novatech S.A.
510(k) Number:	K151832
Product Code/Regulation Number:	GCJ/876.1500 Endoscope and Accessories

No reference devices were used in this submission.

NOVATECH® TALCAIR™ (510(k) number - K151832) is approved for the indication: "*Treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural fluid"*. NOVATECH S.A. is submitting this 510(k) notification to add that the device is intended for manual insufflation of medical grade talc into the pleural cavity during pleurodesis. The device is indicated for use according to the approved indication for use of the medical grade talc.

In addition, NOVATECH S.A. is using NOVATECH® TALCAIR™ (approved under K151832) as a predicate device for this submission. The device remains exactly the same with only the addition of a new indication.

4 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 device is intended for manual insufflation of medical grade talc into the pleural cavity during pleurodesis. The device is indicated for use according to the approved indication for use of the medical grade talc.

5 Indication for Use

The device is intended for manual insufflation of medical grade talc into the pleural cavity during pleurodesis. The device is indicated for use according to the approved indication for use of the medical grade talc.

6 Comparison of technological characteristics with the predicate device

The NOVATECH® TALCAIR™ has the same operating principle and incorporates the same basic design as the predicate device, the NOVATECH® TALCAIR™. A summary

of the technological characteristics of NOVATECH® TALCAIR™ compared to NOVATECH® TALCAIR™ is provided below.

Tabular Comparison to Predicate Device

Item	Proposed Device: NOVATECH® TALCAIR™	Predicate Device: NOVATECH® TALCAIR™
Product Code	GCJ	Same
Regulation Number	876.1500	Same
Class	2	Same
Intended Use	The device is intended for manual insufflation of medical grade talc into the pleural cavity during pleurodesis. The device is indicated for use according to the approved indication for use of the medical grade talc.	Administration of medical grade talc via thoracoscopy. The device is intended to treat patients with malignant pleural effusion.
Indication for Use	The device is intended for manual insufflation of medical grade talc into the pleural cavity during pleurodesis. The device is indicated for use according to the approved indication for use of the medical grade talc.	Treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural fluid.
Patient Population	Adults diagnosed with any of the indications approved for the medical grade talc that requires manual insufflation of medical grade talc into the pleural cavity during pleurodesis.	Those diagnosed with malignant pleural effusion.
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 pleurodesis 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 0.118 inches (3 mm).	Same

	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.	
Materials	PVC, Polyethylene, Polycarbonate	Same
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.	Same
Sterility	NOVATECH® TALCAIR™ is supplied sterile and is intended for single use according to the sterilization validation of the product.	Same
Shelf Life	5 years	Same

7 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 Process 2 (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

Not applicable, NOVATECH S.A. is submitting this 510(k) notification to add the indication that the device is intended for manual insufflation of medical grade talc into the pleural cavity during pleurodesis. The device is indicated for use according to the approved indication for use of the medical grade talc. NOVATECH S.A. is using NOVATECH® TALCAIR™ (approved under K151832) as a predicate device. The device will remain exactly the same with only the addition of a new indication. However, a summary of Bench Performance testing data from K151832 submission is provided below.

Benchmark performance tests on NOVATECH® TALCAIR™ aims 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.

8 Shelf Life / Sterilization

Transport Validation

A sterile barrier test after distribution transport simulation was performed on NOVATECH® TALCAIR™. The purpose of this evaluation was to demonstrate that the sterile barrier of the primary package remains intact using the actual materials, sealing parameters, secondary packaging, usual shipping boxes and configurations.

To validate the sterile sealing seam a 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.

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

9 Conclusion

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

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