April 12, 2018

To
Division of Dockets Management,
Department of Health and Human Services,
U.S. Food and Drug Administration,
5630 Fishers Lane, Room 1061,
Rockville, MD 20857.

Subject: Submission of a '**Citizen Petition**' to request the FDA Commissioner **for reclassification of medical devices associated with FDA Medical Device Product Code NCD**

To whom it may concern,

The undersigned submits this petition for requesting reclassification of the medical devices associated with FDA Medical Device Product Code NCD (**Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis**).

These devices are **currently classified into Class III** subject to PMA under Section 513(f)(1) of the FD&C Act.

This **petition** is being submitted in accordance with the provisions of Section 513(f)(3) of the FD&C Act) **for reclassification** of these devices **to Class II** subject to 510k (Special Controls).

We believe that this petition contains all the required information in the format prescribed by 21CFR10.30.

However, should you have any questions or require additional information, please contact the undersigned by e-mail.

We request for your earliest attention to and favorable decision on this petition.

Thank you for your time and consideration.

Sincerely yours,

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Petition submitted by Boditech Med Inc., South Korea for requesting reclassification of medical devices associated with Product Code NCD

Table of Contents

Petition submitted by Boditech Med Inc., South Korea for requesting reclassification of medical devices associated with Product Code NCD

Section A: Action Requested

The petitioner requests the FDA Commissioner to take all administrative actions required for reclassification of the medical devices associated with Product Code NCD; the FDA regulatory classification details of which as on April 9, 2019, are as follows:

FDA Home[3] Medical Devices[4] Databases[5]

Product Classification

New Search | Back to Search Results

Device	Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis
Review Panel	Microbiology
Product Code	NCD
Premarket Review	Office of In Vitro Diagnostics and Radiological Health[6] (OIR)
Submission Type	PMA
Device Class	3
Total Product Life Cycle (TPLC)	TPLC Product Code Report[7]
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Table A.1 on the next page provides the list of FDA-approved medical devices associated with FDA Product Code: NCD as on April 9, 2019.

These devices are currently classified into Class III subject to premarket approval under Section 513(f)(1) of the FD&C Act.

This petition is being submitted for reclassification of all the devices associated with FDA Product Code: NCD from Class III (subject to pre-market approval) into Class II subject to 510k pre-market notification (special controls).

Table A.1			
List of FDA-approved medical devices (as on April 9, 2019) associated with Product Code: NCD			
No.	**Device name**	**Applicant**	**PMA Number**
1.	Quanttferon-Tb Gold And Tb Gold-In-The-Tube	Qiagen	P010033
2.	Quantiferon-Tb	Qiagen	P010033 S001
3.	Quantiferon-Tb	Qiagen	P010033 S002
4.	Quantiferon-Tb	Qiagen	P010033 S003
5.	Quantiferon-Tb Analysis Software Program	Qiagen	P010033 S004
6.	Quantiferon-Tb Kit	Qiagen	P010033 S005
7.	Quantiferon -Tb Gold	Qiagen	P010033 S006
8.	Quantiferon - Tb	Qiagen	P010033 S007
9.	Quantiferon -Tb Gold	Qiagen	P010033 S009
10.	Quantiferon-Tb Gold	Qiagen	P010033 S010
11.	Quantiferon Tb Gold In Tube	Qiagen	P010033 S011
12.	Quantiferon Tb Gold	Qiagen	P010033 S012
13.	Quantiferon - Tb Gold-In-Tube	Qiagen	P010033 S013
14.	Quantiferon - Tb Gold And Tb Gold In-Tube	Qiagen	P010033 S014
15.	Quantiferon - Tb Gold In-Tube	Qiagen	P010033 S015
16.	Quantiferon-Tb Gold In-Tube	Qiagen	P010033 S016
17.	Quantiferon-Tb Gold In-Tube	Qiagen	P010033 S017
18.	Quantiferon-Tb Gold	Qiagen	P010033 S018
19.	Quantiferon -Tb Gold	Qiagen	P010033 S019
20.	Quantiferon -Tb Gold	Qiagen	P010033 S020
21.	Quantiferon -Tb Gold	Qiagen	P010033 S023
22.	Quantiferon Tb Gold In-Tube	Qiagen	P010033 S024
23.	Quantiferon- Tb Gold Test	Qiagen	P010033 S025
24.	Quantiferon-Tb Gold Test	Qiagen	P010033 S026
25.	Quanttferon-Tb Gold And Tb Gold-In-The-Tube	Qiagen	P010033 S028
26.	Quantiferon-Tb Gold And Tb Gold Test (Reference Lab Pack)	Qiagen	P010033 S029
27.	Quantiferon-Tb Gold And Tb Gold- Test (Reference Lab Pack)	Qiagen	P010033 S030
28.	Quanttferon-Tb Gold Plus	Qiagen	P010033 S031
29.	Quantiferon-Tb Gold Test	Qiagen	P010033 S032
30.	Quanttferon-Tb Gold	Qiagen	P010033 S033
31.	Quantiferon Tb Gold	Qiagen	P010033 S034
32.	Quantiferon - Tb Gold Test And Tb Gold Plus Test	Qiagen	P010033 S035
33.	Quantiferon-Tb Gold And Quantiferon -Tb Gold Plus.	Qiagen	P010033 S036
34.	Quantiferon Tb Gold And Quantiferon Tb Gold Plus	Qiagen	P010033 S037
35.	Quantiferon Tb Gold And Quantiferon Tb Gold Plus	Qiagen	P010033 S038
36.	Quantiferon-Tb Gold And Quantiferon-Tb Gold Plus	Qiagen	P010033 S039
37.	Quantiferon Tb Gold Test, Quantiferon Tb Gold Test (Referenc...	Qiagen	P010033 S040
38.	Quantiferon-Tb Gold Test / Quantiferon Tb Gold Plus Test	Qiagen	P010033 S041
39.	Quantiferon - Tb Gold Test, Quantiferon - Tb Gold Plus Test	Qiagen	P010033 S042
40.	Tb Gold And Quantiferon - Tb Gold Plus	Qiagen	P010033 S043

Accordingly, the petitioner is requesting the FDA Commissioner to take following actions:

1. To take all administrative actions ultimately resulting in reclassification of the medical devices associated with Product Code NCD currently classified into Class III (subject to premarket approval) into Class II subject to 510k pre-market notification (special controls)
2. To establish special controls and issue special controls guidance or guideline to mitigate the risks associated with these devices in order to provide reasonable assurance of safety and effectiveness of the devices associated with Product Code NCD
3. To further take any other form of administrative action necessary to effectuate the aforesaid actions

Petition submitted by Boditech Med Inc., South Korea for requesting reclassification of medical devices associated with Product Code NCD

Section B: Statement of Grounds

B.1 Factual Grounds on which the petition relies:

As on the April 12, 2019, all FDA-approved medical devices associated with the FDA Medical Device Product Code NCD are actually serial modifications to the single original device with following regulatory classification and pre-market approval details:

New Search | Back to Search Results

Note: this medical device has supplements. The device description/function or indication may have changed. Be sure to look at the supplements to get an up-to-date information on device changes. The labeling included below is the version at time of approval of the original PMA or panel track supplement and *may not represent the most recent labeling.*

Device	QUANTTFERON-TB GOLD AND TB GOLD-IN-THE-TUBE
Classification Name	Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis
Generic Name	Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis
Applicant	QIAGEN 19300 Germantown Road Germantown, MD 20874
PMA Number	P010033
Date Received	06/01/2001
Decision Date	11/28/2001
Product Code	NCD [Registered Establishments With NCD]
Docket Number	02M-0218
Notice Date	05/13/2002
Advisory Committee	Microbiology
Expedited Review Granted?	Yes
Combination Product	No
Recalls	CDRH Recalls

Approval Order Statement

APPROVAL FOR THE CELLESTIS QUANTIFERON-TB. THE DEVICE IS INDICATED FOR USE AS AN AID IN THE DETECTION OF INFECTION WITH MYCOBACTERIUM TUBERCULOSIS.

Approval Order	Approval Order
Summary	Summary Of Safety And Effectiveness
Labeling	Labeling
Supplements:	S001 S002 S003 S004 S005 S006 S007 S009 S010 S011 S012 S013 S014 S015 S016 S017 S018 S019 S020 S023 S024 S025 S026 S028 S029 S030 S031 S032 S033 S034 S035 S036 S037 S038 S039 S040 S041 S042 S043

Above details are available on the following link:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010033

The parent device QuantiFERON®-TB test (Quantiferon-Tb Gold and Tb Gold-in-the-Tube, PMA Number P010033) was a post-amendment device of a new type that FDA had not previously classified based on the criteria at section 513(a)(1) of the FD&C Act.

Hence, the petitioner strongly believes that, this device might have been "automatically" or "statutorily" classified into class III by operation of section 513(f)(1) of the FD&C Act regardless of the level of risk(s) it posed or the ability of general and special controls to assure its safety and effectiveness.

Furthermore, since the approval of QuantiFERON®-TB test in November 2001, as no other manufacturer intended to market any similar device in US, there is no similar device with same intended use which has been classified into Class II subject to 510k pre-market notification (special controls) through the "De Novo classification process" in accordance with section 513(f)(2) of the FD&C Act.

B.2 Legal Grounds on which the petition relies:

Under Section 513(f)(3), for a post-amendment device classified automatically into class III under Section 513(f)(1), FDA may initiate a reclassification or respond to a petition from an interested person (including a person who is not a citizen of the United States) who requests reclassification of a device type from Class III to either class I or II in accordance with the provisions of Section 513(f)(3) of the FD&C Act.

Section 513(e) of the FD&C Act provides that FDA can initiate a reclassification and may, by administrative order, reclassify a device based on "new information" in response to a reclassification petition from interested person.

The term "new information," as used in section 513(e), includes information developed as a result of a reevaluation of the data before FDA when the device was originally classified; as well as information not presented, not available, or not developed at that time.

B.3 Petitioner's views for disagreement with present classification status of the device:

QuantiFERON®-TB test (Quantiferon-Tb Gold and Tb Gold-in-the-Tube); the original device with Product Code NCD was approved by FDA in 2001 as a class III device (PMA Number P010033).

FDA-approved intended use of and suitable populations for the originally approved QuantiFERON®-TB test are as follows:

The QuantiFERON-TB test is an in-vitro diagnostic test intended as an aid in the detection of infection with Mycobacterium tuberculosis. It should not be the sole basis for determining infection and results must be interpreted with all other clinical and historical patient data to determine the risk of TB infection. A negative QuantiFERON-TB result does not preclude the possibility of TB infection.

The QuantiFERON-TB test has been evaluated for use with immunocompetent healthy adults with and without identified risk factors for latent TB infection (LTBI). QuantiFERON-TB has also been evaluated in individuals with culture-proven TB disease.

QuantiFERON-TB can be used for people who are being tested for TB infection, with the following limitations.

- *The test has not been evaluated for use with children, infants, adolescents (< 17 years), pregnant women, immunocompromised individuals (including HIV positive individuals), or people with clinical conditions predisposing immunosuppression (i.e. diabetes, silicosis, cancers, organ transplants), or those taking immunosuppressive medication.*
- *Care should be taken when interpreting QuantiFERON-TB results in individuals who have received a tuberculin skin test (TST or Mantoux) within the last 12 months as QuantiFERON-TB results may be boosted or falsely positive following prior skin testing, and the effects of the TST on subsequent QuantiFERON-TB results has not been evaluated.*

QuantiFERON®-TB test was subsequently modified to QuantiFERON®-TB Gold (QFT®) test having following FDA-approved intended use:

QuantiFERON-TB Gold (QFT®) is an in vitro diagnostic test using a peptide cocktail simulating ESAT-6, CFP-10, and TB7.7(p4) proteins to stimulate cells in heparinized whole blood. Detection of interferon-γ (IFN-γ) by enzyme-linked immunosorbent assay (ELISA) is used to identify in vitro responses to those peptide antigens that are associated with *Mycobacterium tuberculosis* infection.

QFT is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

QuantiFERON®-TB Gold test has been subsequently modified to QuantiFERON®-TB Gold Plus (QFT® Plus) test having following FDA-approved intended use:

The QuantiFERON-TB Gold Plus (QFT-Plus) assay is an in vitro diagnostic test using a peptide cocktail simulating ESAT-6 and CFP-10 proteins to stimulate cells in heparinized whole blood. Detection of interferon-γ (IFN-γ) by enzyme-linked immunosorbent assay (ELISA) is used to identify in vitro responses to those peptide antigens that are associated with *Mycobacterium tuberculosis* infection.

QFT-Plus is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

FDA has approved following warnings for QuantiFERON®-TB Gold as well as QuantiFERON®-TB Gold Plus tests:

- A negative QFT result does not preclude the possibility of *M. tuberculosis* infection or tuberculosis disease: false negative results can be due to stage of infection (e.g., specimen obtained prior to the development of cellular immune response), co-morbid conditions which affect immune functions, incorrect handling of the blood collection tubes following venipuncture, incorrect performance of the assay, or other immunological variables.
- A positive QFT result should not be the sole or definitive basis for determining infection with *M. tuberculosis*. Incorrect performance of the assay may cause false-positive responses.
- A positive QFT result should be followed by further medical evaluation and diagnostic evaluation for active tuberculosis disease (e.g., AFB smear and culture, chest X-ray).
- While ESAT-6, CFP-10, and TB7.7(p4) are absent from all BCG strains and from most known nontuberculous mycobacteria, it is possible that a positive QFT result may be due to infection by *M. kansasii*, *M. szulgai*, or *M. marinum*. If such infections are suspected, alternative tests should be investigated.

It is evident that test results of none of the FDA-approved tests associated with FDA-Product Code NCD are to be regarded as the sole basis for determining presence or absence of *M. tuberculosis* infection or disease.

QuantiFERON®-TB test results must be interpreted with all other clinical and historical patient data to determine the risk of TB infection.

Similarly, a positive QuantiFERON®-TB Gold or QuantiFERON®-TB Gold Plus test result needs to be followed by further medical evaluation and diagnostic evaluation (e.g. AFB smear and culture, chest X-ray etc.) for diagnosis active tuberculosis.

Hence, the devices associated with FDA Product Code NCD do present a potential, unreasonable risk of illness or injury. Moreover, these devices do not support or sustain human life and are not of substantial importance in preventing impairment of human health.

Thus, it is obvious that there is no high risk(s) of false negative or false positive test results of any of the devices currently approved with FDA Product Code NCD.

These devices have been “automatically” or “statutorily” classified into class III by operation of section 513(f)(1) of the FD&C Act regardless of the level of risk(s) it posed or the ability of general and special controls to assure their safety and effectiveness.

Furthermore, since the approval of QuantiFERON®-TB test (Quantiferon-Tb Gold and Tb Gold-in-the-Tube, PMA Number P010033) in November 2001, as no other manufacturer intended to market any similar device in US, there is no similar device with same intended use which has been classified into Class II subject to 510k pre-market notification (special controls) through the "De Novo classification process" in accordance with section 513(f)(2) of the FD&C Act.

To the best of petitioner's knowledge, no person has filed a Citizen Petition till date requesting the FDA Commissioner to reclassify the devices associated with FDA Product Code: NCD from Class III (subject to pre-market approval) into Class II subject to 510k pre-market notification (special controls).

The petitioner strongly believes that, special controls along with general controls can adequately mitigate the risks associated these devices to reasonably assure the safety and effectiveness of these devices.

Hence, Class II subject to 510k pre-market notification (special controls) is the most appropriate FDA regulatory classification for the medical devices associated with Product Code NCD which are currently classified as Class III devices subject to pre-market approval.

B.4 Relevant information in support of requested classification status of the device:

Section 513(e) of the FD&C Act provides that FDA can initiate a reclassification and may, by administrative order, reclassify a device based on "new information" in response to a reclassification petition from interested person.

The term "new information" as used in section 513(e), includes information developed as a result of a reevaluation of the data before FDA when the device was originally classified; as well as information not presented, not available, or not developed at that time.

The petitioner believes that information discussed in this section qualifies as "valid scientific evidence' as defined in 21CFR860.7 for the purpose of determining the safety and effectiveness of the medical devices associated with Product Code NCD in light of requested reclassification of these devices from Class III (subject to pre-market approval) to Class II subject to 510k pre-market notification (special controls).

The petitioner also believes that "valid scientific evidence' discussed in this section along with other evidence which may be available with FDA, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the devices associated with Product Code NCD will be safe and effective for their intended uses and conditions of use even after their reclassification from Class III (subject to pre-market approval) to Class II subject to 510k pre-market notification (special controls).

The sponsor strongly believes that, even after reclassification of the devices associated with Product Code NCD to Class II subject to 510k pre-market notification (special controls), probable benefits to health from use of these devices for their its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, will outweigh any probable residual risks.

Following is the summary of relevant information being submitted by the petitioner which the petitioner believes, qualifies as "valid scientific evidence" in support of requested reclassification of the medical devices associated with Product Code NCD from Class III (subject to pre-market approval) to Class II subject to 510k pre-market notification (special controls):

B.4.1 Well-established safety and effectiveness of medical devices associated with Product Code NCD

QuantiFERON®-TB test (Quantiferon-Tb Gold and Tb Gold-in-the-Tube); the original device with Product Code NCD, was approved by FDA in November 2001 as a class III device (PMA Number P010033). It is intended as an aid in the detection of infection with Mycobacterium tuberculosis.

QuantiFERON®-TB test was subsequently modified to QuantiFERON®-TB Gold (QFT®) test which was approved by FDA in 2005 as an indirect test for *M. Tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

QuantiFERON®-TB Gold Plus test (QFT® Plus) is the latest modification approved by FDA in June 2017 and it has the same intended use as that of QuantiFERON®-TB Gold (QFT®) test.

In addition to US where more than five million QuantiFERON®-TB Gold Plus tests were sold in 2015, these tests are marketed in more than 75 countries across Europe, the Middle East, Africa, Asia and Latin America.

Both FDA and clinicians have come to better understand the risks, benefits and limitations of the devices associated with Product Code NCD. **As the risk profile of these devices has become more apparent, FDA should revisit their classification to ensure that reasonable controls are being applied to ensure existing and new products are both safe and effective for their intended uses**.

Hence, Class II subject to 510k pre-market notification (special controls) is the most appropriate FDA regulatory classification for the medical devices associated with Product Code NCD which are currently classified as Class III devices subject to pre-market approval.

B.4.2 Release of the 2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children by Centers for Disease Control and Prevention:

The Centers for Disease Control and Prevention released the "**2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children"** (Appendix I) which were developed by the CDC, the American Thoracic Society and the Infectious Diseases Society of America and endorsed by the European Respiratory Society.

The guidelines update the previous tuberculosis diagnostics guidelines published by ATS/CDC/IDSA in 2000.The guidelines provide recommendations on the diagnosis of latent TB infection, pulmonary TB and extrapulmonary TB in adults and children.

The 23 evidence-based recommendations include guidance for clinicians on how to employ newer tests to diagnose TB disease and latent TB infection, including interferon-gamma release assays (IGRAs) and molecular diagnostics.

These recommendations were developed with the GRADE methodology, which involves structured literature review, systematic reviews and meta-analyses of combined data, and expert discussion to assess the certainty in the evidence and determine the strength of each recommendation.

These guidelines have broadened the preferential recommendation for the use of modern blood-based TB tests (tests based on interferon gamma release, or IGRAs) over the 100-year-old tuberculin skin test (TST) in a wider group of people at risk for latent or active tuberculosis infection.

This expanded preferential recommendation is expected to drive more rapid conversion from the use of the TST given that these guidelines are the first of their kind to recommend IGRAs over the TST based on disease progression risk, and not just based on patient types.

In testing for latent tuberculosis infection (LTBI), a condition that produces no symptoms but can progress to the active form of TB, the task force strongly recommended performing an IGRA instead of the TST in people age 5 and older who are likely to be infected with the Mycobacterium tuberculosis bacteria that causes the disease as well as those with a low to intermediate risk of progression to active TB.

The guidelines also supported the use of an IGRA in people for whom it has been decided that latent TB testing is warranted, and also those who either have been vaccinated with the BCG vaccine against TB or are unlikely to return for the required second visit for a TST test.

Furthermore, the task force agreed with current U.S. guidelines that people at low risk for TB infection should not be tested, but any test performed in this group should be with an IGRA instead of a TST. The guidelines also recommended that children age 5 and younger continue to be tested with a TST but can also be tested with an IGRA.

The publication of these guidelines follows the announcement in September 2016 of recommendations by the U.S. Preventive Services Task Force (USPSTF) that primary care physicians screen adult patients in groups at high risk for latent TB infections.

The final USPSTF recommendations referred to QuantiFERON-TB Gold as reliable in screening and suggested IGRAs may be preferable in certain patient groups than the TST.

The recommendation for use of IGRAs for screening for latent TB infections in primary care settings establishes the fact that the devices associated with Product Code NCD do not have high risk(s) and special controls along with general controls can adequately mitigate the risks associated these devices to reasonably assure their safety and effectiveness.

Hence, Class II subject to 510k pre-market notification (special controls) is the most appropriate FDA regulatory classification for the medical devices associated with Product Code NCD which are currently classified as Class III devices subject to pre-market approval.

B.4.3 Release of updated guidelines for management of Latent TB in February 2018 by WHO:

In February 2018, WHO issued updated and consolidated guidelines for programmatic management of Latent TB infection (Appendix II) superseding previous WHO policy documents on the management of Latent TB infection (LTBI) in people living with HIV, household contacts of people with active TB, other groups at risk of developing TB, and for LTBI testing.

WHO's previous recommendations prioritized testing and treatment for people living with HIV and children aged younger than 5 years who are in contacts with TB patients.

WHO now considers all patients exposed to TB or multidrug-resistant (MDR)-TB regardless of age or HIV status, as being at high risk and warranting testing and treatment.

The updated guidelines further recommend testing and treating patients who are starting anti-tumor necrosis factor (TNF) treatment, receiving dialysis, or preparing for transplant surgery, as well as those with silicosis.

In countries with a low incidence of TB, testing and treatment may also be considered in prisoners, health care workers, immigrants from TB-endemic countries, homeless people and people who use illicit drugs.

For the first time, WHO has also recommended the use of both commercially available interferon-gamma release assays (IGRA) — QuantiFERON-TB Gold In-Tube (Qiagen) and T-SPOT TB (Oxford Immunotec) — in addition to tuberculin skin tests (TSTs) in resource-limited settings.

In 2011, WHO released a policy statement claiming there were not enough data to confirm how IGRAs performed in low- and middle-income countries with a high TB and HIV burden. However, a more recent meta-analysis involving more than 7,700 participants showed that IGRAs were associated with a "slightly higher" predictive performance than TST, with a pooled risk ratio estimate of 2.03 (95% CI, 1.18-3.50) vs. 1.49 (95% CI, 0.79-2.80).

WHO's updated guidelines recommending use of IGRAs for screening for latent TB infections in resource-limited settings establishes the fact that the devices associated

with Product Code NCD do not have high risk(s) and special controls along with general controls can adequately mitigate the risks associated these devices to reasonably assure their safety and effectiveness.

Hence, Class II subject to 510k pre-market notification (special controls) is the most appropriate FDA regulatory classification for the medical devices associated with Product Code NCD which are currently classified as Class III devices subject to pre-market approval.

B.4.3 Reclassification of Nucleic Acid-Based Systems for *Mycobacterium tuberculosis* Complex in Respiratory Specimens from Class III to Class II in 2014 by FDA:

In May 2014, FDA reclassified Nucleic Acid-Based Systems for *Mycobacterium tuberculosis* Complex in Respiratory Specimens from Class III subject to pre-market approval to Class II subject to 510k pre-market notification (special controls).

FDA also issued the special controls guideline entitled ‘‘Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens.’’ (Appendix III)

These devices have now been classified under 21 CFR 866.3372 with following details:

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2018]
[CITE: 21CFR866.3372]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 866 -- IMMUNOLOGY AND MICROBIOLOGY DEVICES

Subpart D--Serological Reagents

Sec. 866.3372 Nucleic acid-based in vitro diagnostic devices for the detection of Mycobacterium tuberculosis complex in respiratory specimens.

(a) *Identification.* Nucleic acid-based in vitro diagnostic devices for the detection of *Mycobacterium tuberculosis* complex in respiratory specimens are qualitative nucleic acid-based in vitro diagnostic devices intended to detect *Mycobacterium tuberculosis* complex nucleic acids extracted from human respiratory specimens. These devices are non-multiplexed and intended to be used as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. These devices do not include devices intended to detect the presence of organism mutations associated with drug resistance. Respiratory specimens may include sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavage or bronchial aspirate), or tracheal aspirates.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA document entitled "Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens." For availability of the guideline document, see 866.1(e).

[79 FR 31027, May 30, 2014]

Risk(s) associated with the use of devices associated with Product Code NCD is certainly not higher than that associated with the Nucleic Acid-Based Systems for *Mycobacterium tuberculosis* Complex in Respiratory Specimens reclassified to Class II under 21 CFR 866.3372.

Accordingly, special controls along with general controls can adequately mitigate the risks associated these devices to reasonably assure their safety and effectiveness.

Hence, Class II subject to 510k pre-market notification (special controls) is the most appropriate FDA regulatory classification for the medical devices associated with Product Code NCD which are currently classified as Class III devices subject to pre-market approval.

B.5 Representative information known to the petitioner which is unfavorable to the petitioner's position:

To the best of petitioner’s knowledge and understanding, there is no information known to the petitioner which is unfavorable to the petitioner’s position.

Petition submitted by Boditech Med Inc., South Korea for requesting reclassification of medical devices associated with Product Code NCD

Section C: Environmental Impact

The action requested in this petition is essentially the reclassification of a medical device (including the establishment of special controls) under 21 C.F.R. Part 860: Medical Device Classification.

The petitioner strongly believes that, even if FDA effectuates the action requested in this petition, that action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

Thus, the action requested in this petition is a 'categorically excluded action' as it fully meets the criteria described in Section 25.34(b) under Subpart C of 21CFR25.

Hence, the petitioner hereby states that the action requested in this petition will have no environmental impact and that, therefore, the petitioner does not need to prepare an environmental assessment (EA) as per Section 25.40 and/or an environmental impact statement (EIS) as per Section 25.42 under Subpart D of 21CFR25.

Petition submitted by Boditech Med Inc., South Korea for requesting reclassification of medical devices associated with Product Code NCD

Section D: Economic Impact

The petitioner is aware that, during or after review of the petition by FDA, the petitioner may need to submit the following information as per 21 CFR Section 10.30(b)(3E):

- A statement of the effect of requested action on:
    1. Cost (and price) increases to industry, government, and consumers;
    2. Productivity of wage earners, businesses, or government;
    3. Competition;
    4. Supplies of important materials, products, or services;
    5. Employment; and
    6. Energy supply or demand

However, the sponsor believes that above information is to be submitted only when requested by the FDA Commissioner following the review of this petition.

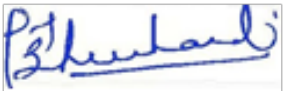
Accordingly, the petitioner will be pleased to submit all or any of the above economic impact information as and when requested by the FDA.

Petition submitted by Boditech Med Inc., South Korea for requesting reclassification of medical devices associated with Product Code NCD

Section E: Certification

To whom it may concern

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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