November 12, 2021

Sebia
Karen Anderson
Director of Regulatory
1705 Corporate Drive Suite 400
Norcross, Georgia 30096

Re: K203184
Trade/Device Name: HYDRASHIFT 2/4 isatuximab
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E Immunological Test System
Regulatory Class: Class II
Product Code: CFF
Dated: October 15, 2020
Received: October 27, 2020

Dear Karen Anderson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao, Ph.D.
Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203184

Device Name
HYDRASHIFT 2/4 isatuximab

Indications for Use *(Describe)*

The HYDRASHIFT 2/4 isatuximab kit is intended for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. The HYDRASHIFT 2/4 isatuximab kit is to be used in conjunction with the HYDRAGEL IF kit and the semi-automated HYDRASYS 2 electrophoresis apparatus. The electropherograms are evaluated visually for the presence of specific reactions with the suspect monoclonal proteins. The HYDRASHIFT 2/4 isatuximab kit removes isatuximab IgG kappa interference and enables the visual evaluation of the presence or absence of monoclonal proteins on HYDRAGEL IF kits in patients who have received isatuximab therapy.

For In Vitro Diagnostic use. For Prescription Use Only.

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.

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510K SUMMARY (Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	Sebia
Address	1705 Corporate Drive Suite 400 Norcross, Georgia 30093, USA
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Date Prepared	November 9, 2021
Manufacturing	Sebia Parc Technologique Léonard de Vinci Rue Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex FRANCE Phone: (33) 1 69 89 80 80 Fax: (33) 1 69 89 78 78
Product Name	HYDRASHIFT 2/4 isatuximab
Common Name	Hydrashift isatuximab Serum Immunofixation
Product Regulation No.	21CFR sec. 866.5510

Product Codes	CFF
Device classification and Panel Classification	Class II, Immunology
Establishment Registration No.	8023024

1. DEVICE DESCRIPTION

HYDRASYS 2 is a semi-automated multi-parameter system for start-to finish agarose gel electrophoresis: application of samples, migration, incubation, drying, staining, destaining and final-stage drying.

Abnormal bands in serum protein electrophoregrams, primarily those in the beta globulin and gamma globulin zones, are always suspected to be monoclonal proteins (M-proteins, paraproteins, monoclonal immunoglobulins) and therefore, an indication of performing an Immunofixation technique to type and confirm the monoclonal gammopathies.

Isatuximab is a human therapeutic IgG kappa monoclonal antibody and as such, during the clinical monitoring of patients treated with isatuximab, this antibody simulates a band detected by serum protein electrophoresis and immunofixation in the gamma region. It can simulate an endogenous IgG kappa paraprotein.

Reagents:
REAGENTS AND MATERIALS SUPPLIED IN THE HYDRASHIFT 2/4 isatuximab KIT

ITEMS	PN 4642(40 TESTS)
Anti-isatuximab antiserum (ready to use)	1 vial, 0.8 mL
Sample diluent (ready to use)	1 vial, 2,2 mL
Green applicators (ready to use)	2 packs of 10 (15 teeth)

REAGENTS REQUIRED BUT NOT SUPPLIED

	SEBIA PRODUCT NUMBER
HYDRAGEL 2 or 4 IF Acid violet - Dynamic mask	4302, 4304 or 4381*
Antisera and Fixative for immunofixation IF - Dynamic mask	4315
or	

HYDRAGEL 2 or 4 IF Acid violet - Standard mask	4802, 4804 or 4881*
Antisera and Fixative for immunofixation IF - Standard mask	4815
and	
isatuximab CONTROL	4764
DESTAINING SOLUTION	4540
HYDRASYS WASH SOLUTION	4541
HYDRAGEL IF SAMPLE DILUENT	4588
FLUIDIL	4587
DTT DILUENT (IF / IT)	4589
BETA-MERCAPTOETHANOL (BME or 2MERCAPTOETHANOL)	Not supplied by SEBIA

2. INDICATIONS FOR USE

The HYDRASHIFT 2/4 isatuximab kit is intended for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. The HYDRASHIFT 2/4 isatuximab kit is to be used in conjunction with the HYDRAGEL IF kit and the semi-automated HYDRASYS 2 electrophoresis apparatus. The electropherograms are evaluated visually for the presence of specific reactions with the suspect monoclonal proteins. The HYDRASHIFT 2/4 isatuximab kit removes isatuximab IgG kappa interference and enables the visual evaluation of the presence or absence of monoclonal proteins on HYDRAGEL IF kits in patients who have received isatuximab therapy.

For *In Vitro* Diagnostic use. For Prescription Use Only.

3. TECHNOLOGICAL CHARACTERISTICS

The HYDRASHIFT isatuximab immunofixation procedure, performed on the HYDRAGEL IF 2/4 gel, is based on the creation of an isatuximab / anti-isatuximab antibody complex and shifting it outside the gammaglobulins zone. With the HYDRASHIFT isatuximab procedure, the isatuximab / anti-isatuximab antibody complex is visualized in alpha-1 zone on IgG and Kappa immunofixation tracks and then the interference is removed from the gamma zone.

4. SUBSTANTIAL EQUIVALENCE INFORMATION:

Predicate Device Name	Predicate Device 510(k) number	Product Code	Regulation No.
HYDRAGEL IF	K960669	CFF	866.5510

Similarities between the candidate device (HYDRASHIFT 2/4 isatxumiab) and the predicate device (HYDRAGEL IF) (Table A).

Similarities		
Table A	HYDRASHIFT 2/4 isatuximab **Candidate Device**	HYDRAGEL IF **Predicate Device** **K960669**
Intended Use / Indications For Use	The HYDRASHIFT 2/4 isatuximab kit is intended for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. The HYDRASHIFT 2/4 isatuximab kit is to be used in conjunction with the HYDRAGEL IF kit and the semi-automated HYDRASYS 2 electrophoresis apparatus. The electropherograms are evaluated visually for the presence of specific reactions with the suspect monoclonal proteins. The HYDRASHIFT 2/4 isatuximab kit removes isatuximab IgG kappa interference and enables the visual evaluation of the presence or absence of monoclonal proteins on HYDRAGEL IF kits in patients who have received isatuximab therapy. For *In Vitro* Diagnostic use. For Prescription Use Only.	The HYDRAGEL 1 IF, 2 IF, 4 IF and 9 IF kits are designed for detection of monoclonal proteins in human serum and urine by immunofixation electrophoresis. The kits are used in conjunction with the semi-automated HYDRASYS electrophoresis apparatus. The proteins, separated by electrophoresis on alkaline buffered agarose gels, are incubated with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) and lambda (free and bound) light chains, respectively. After removing the non-reacted proteins, the immunoprecipitates are stained either with acid violet or amidoblack. The electrophoregrams are evaluated visually for the presence of specific reactions with the suspect monoclonal proteins.
Assay Principle	Agarose Gel Electrophoresis	Agarose Gel Electrophoresis
Software Program	Same	IF Program

Table B. Differences between the predicate device (HYDRAGEL IF) and the candidate device (HYDRASHIFT 2/4 isatuximab) in (Table B).

Differences		
Table B	HYDRASHIFT 2/4 isatuximab **Candidate Device**	HYDRAGEL IF **Predicate Device K960669**
Specimen Type	Human Serum	Human Serum, Human Urine
Reagents	Using anti-isatuximab antibody	No anti-isatuximab antibody
isatuximab band	Removed from gamma zone into alpha zone	Remains in Gamma zone

5. Performance Data:

a) Repeatability

Ten (10) different samples, including two (2) samples without the addition of isatuximab (isatuximab CONTROL and Normal Control Serum) and 8 samples with addition of isatuximab (samples 3 to 10 with monoclonal component).
Samples 3 to 10 were also analyzed native to verify the concordance between native and spiked samples were run using the HYDRASHIFT 2/4 isatuximiab procedure used in conjunction with each of the following kits- HYDRAGEL 4 IF Acid violet Standard mask and HYDRAGEL 4 IF Acid Violet Dyamic mask.
Each sample was run 4 times within the same gel.
For each tested sample, all repeats gave 100% concordant results within the gel.

Sample No.	Type	Within gel	Total analyses per gel
Sample No. 1	Isatuximab Control	100% concordant result	4
Sample No. 2	Normal Control	100% concordant result	4
Sample No. 3	IgG kappa	100% concordant result	4
Sample No. 4	IgG lambda	100% concordant result	4
Sample No. 5	IgA kappa	100% concordant result	4
Sample No. 6	IgA lambda	100% concordant result	4

Sample No. 7	IgM kappa	100% concordant result	4
Sample No. 8	IgM lambda + IgA kappa	100% concordant result	4
Sample No. 9	Kappa Free	100% concordant result	4
Sample No. 10	Lambda free	100% concordant result	4

b) Reproducibility between gels, between lots and between instruments

Eight (8) different serum samples with monoclonal components were run using the HYDRASHIFT 2/4 isatuximab procedure used in conjunction with HYDRAGEL 4 IF Acid violet Standard mask and the HYDRAGEL 4 IF Acid violet Dynamic mask

A Normal Control Serum was analyzed on 9 runs with one analysis per gel, over 3 working days, it gave 100 % of concordant results between gels on the 3 HYDRASYS 2 instruments and with 3 lots of HYDRASHIFT 2/4 isatuximab kit over 3 working days

This study was performed with 3 HYDRASYS 2 instruments and with 3 lots of HYDRASHIFT 2/4 isatuximab kit over 3 working days.
Each sample was analyzed on 9 runs with one analysis per gel, over 3 working days. All samples gave 100% concordant results between gels on the 3 HYDRASYS 2 instruments.

Sample No.	Type	Instrument No. 1 / Kit lot No. 1			Instrument No. 2 / Kit lot No. 2			Instrument No. 3 / Kit lot No. 3			Total analyses per sample
		Day No. 1	Day No. 2	Day No. 3	Day No. 1	Day No. 2	Day No. 3	Day No. 1	Day No. 2	Day No. 3	
2	Normal	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
3	IgG kappa	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
4	IgG lambda	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
5	IgA kappa	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
6	IgA lambda	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
7	IgM kappa	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
8	IgM lambda + IgA kappa	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
9	Kappa free	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9
10	Lambda free	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	9

The isatuximab CONTROL was analyzed on 9 runs including one analysis per gel on 3 gels over 3 working days.
The isatuximab CONTROL gave 100% concordant results between gels on the 3 HYDRASYS 2 instruments and with 3 lots of HYDRASHIFT 2/4 isatuximab kit over 3 working days.

Sample No.	Type	Instrument No. 1 / Kit No. 1			Instrument No. 2 / Kit No. 2			Instrument No. 3 / Kit No. 3			Total analyses per sample
		Day No. 1	Day No. 2	Day No. 3	Day No. 1	Day No. 2	Day No. 3	Day No. 1	Day No. 2	Day No. 3	
1	Normal	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	100 % concordant result	27

c) Comparative studies

The results presented below have been obtained from 1 internal study and 2 external studies performed in the USA. The external study No. 1 was performed on 204 samples and the external study No. 2 was performed on 203 samples. The same serum samples were analyzed in both external studies with exception of one sample included in external study 1.

Internal study

The internal study was conducted on 53 serum samples analyzed with HYDRASHIFT 2/4 isatuximab procedure used in conjunction with each of the following kits :
- HYDRAGEL 4 IF Acid violet Standard mask,
- HYDRAGEL 4 IF Acid violet Dynamic mask,
- HYDRAGEL 2 IF Acid violet Standard mask,
- HYDRAGEL 2 IF Acid violet Dynamic mask.

This study, conducted between native samples and the same samples added with isatuximab (spiked samples), demonstrated a 100% complete agreement:
- For 26 normal serum samples: 100% concordant results.
- For 27 pathological serum samples: 100% concordant results.

In both types of samples, monoclonal proteins were detected and characterized with 100 % of concordance.

Characterization	Number of serum samples
Normal	26
IgG kappa	9
IgG lambda	4
IgA kappa	3
IgA lambda	3
IgM kappa	3
IgM lambda	2
Kappa free	3
Total	53

External study No. 1

Comparative study No. 1 was performed on 204 serum samples analyzed with:
- HYDRAGEL 4 IF Acid Violet Dynamic Mask kit,
- HYDRASHIFT 2/4 isatuximab used in conjunction with HYDRAGEL 4 IF Acid Violet Dynamic Mask kit.

With the HYDRAGEL 4 IF Acid Violet Dynamic Mask procedure, the isatuximab was visualized on G track and on Kappa track for 90 samples. For those samples, the HYDRASHIFT 2/4 isatuximab used in conjunction with HYDRAGEL 4 IF Acid Violet Dynamic Mask kit allows the shifting of the isatuximab.

For the other 114 samples, the characterization (normal or abnormal with monoclonal components) was the same between both procedures.

This study demonstrated 100% concordant result:
- For 69 normal serum samples: 100% concordant result.
- For the 135 pathological serum samples: 100% concordant result.

2 IgA kappa	1
2 IgG kappa	2
2 IgM kappa + IgG lambda	1
2 Lambda	1
IgA kappa	17
IgA kappa + IgG kappa	1
IgA lambda	10
IgA lambda + IgG lambda	1
IgA lambda + Lambda	4
IgG kappa	45
IgG kappa + IgG lambda	5
IgG kappa + Kappa	1
IgG kappa + Lambda	2
IgG lambda	29
IgG lambda + Lambda	5
Kappa	2
Lambda	8
Normal	69
Total	204

External study No. 2

Comparative study No. 2 was performed on 203 serum samples analyzed with:
- HYDRAGEL 4 IF Acid Violet Standard Mask kit,
- HYDRASHIFT 2/4 isatuximab used in conjunction with HYDRAGEL 4 IF Acid Violet Standard Mask kit. With the HYDRAGEL 4 IF Acid Violet Standard Mask procedure, the isatuximab was visualized on G track and on Kappa track for 90 samples. For those samples, the HYDRASHIFT 2/4 isatuximab used in conjunction with HYDRAGEL 4 IF Acid Violet Standard Mask kit allows the shifting of the isatuximab.

For the other 113 samples, the characterization (normal or abnormal with monoclonal components) was the same between both procedures.
This study demonstrated 100 % concordant result:
- For 68 normal serum samples: 100 % concordant result.
- For the 135 pathological serum samples: 100 % concordant result.

2 IgA kappa	1
2 IgG kappa	2
2 IgM kappa + IgG lambda	1
2 Lambda	1
IgA kappa	17
IgA kappa + IgG kappa	1
IgA lambda	10
IgA lambda + IgG lambda	1
IgA lambda + Lambda	4
IgG kappa	45
IgG kappa + IgG lambda	5
IgG kappa + Kappa	1
IgG kappa + Lambda	2
IgG lambda	29
IgG lambda + Lambda	5
Kappa	2
Lambda	8
Normal	68
Total	203

d) Sensitivity

Five (5) serum samples, added with isatuximab at different concentrations (final concentrations in sample between 0.1 and 3.0 g/L), were analyzed with the HYDRASHIFT 2/4 isatuximab procedure used in conjunction with each of the following kits:
- HYDRAGEL 4 IF Acid Violet Standard Mask,
- HYDRAGEL 4 IF Acid Violet Dynamic Mask.
The detection limit of isatuximab and / or isatuximab / anti-isatuximab antibody complex visualized is 0.3 g/L.

e) Controls
It is recommended to run assay control serum (such as isatuximab CONTROL, SEBIA PN 4764) after each reagent lot change.

f) Interferences

The common interfering factors with the HYDRASHIFT 2/4 isatuximab procedure (bilirubin, triglycerides, hemoglobin and rheumatoid factor) were evaluated in studies based on the Clinical Laboratory Standards Institute (CLSI-USA) EP07, 3rd ed guideline "Interference Testing in Clinical Chemistry; Third Edition". HAMA (Human Anti-Mouse Antibody) interference testing was also included in the interference study.
Additional inferference studies included: Pomalidomide, Carfilzomib, Dexamethasone, Ixazomib, Cyclophosphamide, Melphalan, Prednisone, Lenalidomide Bortezomib,).
The results are summarized below
No interference with the HYDRASHIFT 2/4 isatuximab procedure was detected due to the serum sample's concentration of the following interfering factors tested at levels equal to the concentrations listed below:

Endogenous Interfering factor	**Concentration**
Unconjugated bilirubin	20 mg/dL (342 µM)
Conjugated bilirubin	20 mg/dL (342 µM)
Triglycerides	3.00 g/dL (33.96 mM)
Hemoglobin	0.2 g/dL
Rheumatoid factor	2000 IU/mL
Human Anti-Mouse Antibody (HAMA)	Titer: 640

Drug Interference

No interference with the HYDRASHIFT 2/4 isatuximab procedure was detected due to the serum sample's high concentration of the following interfering factors tested at levels equal to the concentrations listed below:

Interfering factor	Concentration
Pomalidomide	1 mg/L
Carfilzomib	1 mg/L
Dexamethasone	1 mg/L
Ixazomib	1 mg/L
Cyclophosphamide	1 mg/L
Melphalan	1 mg/L
Prednisone	1 mg/L
Lenalidomide	4 mg/L
Bortezomib	2 mg/L

6. International Myeloma Working Group (IMWG) Response Criteria

As discussed in the current International Myeloma Working Group response criteria guidelines[1] serum protein electrophoresis (SPEP) and Immunofixation (IF) are part of the current IMWG standard of practice recommendations for monitoring responses and relapses in multiple myeloma. International guidelines such as the National Comprehensive Cancer Network Clinical Practice Guidelines for Multiple Myeloma (NCCN) use reductions of monoclonal protein by SPEP and normalization of IFE to stratify response.

1. Kumar S, Paiva B, Anderson KC, Durie B, Landgren O, Moreau P, Munshi N, Lonial S, Bladé J, Mateos MV, Dimopoulos M, Kastritis E, Boccadoro M, Orlowski R, Goldschmidt H, Spencer A, Hou J, Chng WJ, Usmani SZ, Zamagni E, Shimizu K, Jagannath S, Johnsen HE, Terpos E, Reiman A, Kyle RA, Sonneveld P, Richardson PG, McCarthy P, Ludwig H, Chen W, Cavo M, Harousseau JL, Lentzsch S, Hillengass J, Palumbo A, Orfao A, Rajkumar SV, Miguel JS, Avet-Loiseau H. International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma. The Lancet Oncol. 2016 Aug;17(8):e328-e346. doi: 10.1016/S1470-2045(16)30206-6. PMID: 27511158.

7. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.