November 30, 2023

Compumedics Limited
Michael Frischman
Electronics Engineer
30-40 Flockhart St
Abbotsford, Victoria 3067
Australia

Re: K231546
Trade/Device Name: Somfit
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, OMC
Dated: October 30, 2023
Received: October 30, 2023

Dear Michael Frischman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices

OHT5: Office of Neurological
and Physical Medicine Devices
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)*
K231546

Device Name
Somfit

Indications for Use *(Describe)*
The Somfit system is a non-invasive prescription device for home use with patients suspected to have sleep-related breathing disorders. The Somfit is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. The Somfit system acquires electrical data from three frontal electrodes, tri-axial accelerometer data, acoustic and plethysmographic data. The Somfit calculates and reports to clinicians EEG/EOG channels, Sleep Stages, SpO2, Peripheral Arterial Tonometry (PAT) signal, pulse rate, and snoring level. The Somfit calculates and reports to clinicians derived parameters such as PAT-derived Apnea Hypopnea Index, Obstructive Desaturation Index; and hypnogram-derived indices such as time in each sleep stage. Somfit data is not intended to be used as the sole or primary basis for diagnosing any sleep-related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. The Somfit is not intended for use as life support equipment, for example vital signs monitoring in intensive care unit. The Somfit is a prescription device indicated for adult patients aged 21 years and over.

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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510(k) Summary

Device Name: Somfit

The following 510(k) summary is being submitted in accordance with 21 CFR 807.92.

Submission Details

Applicant Information:

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Submission Prepared: 30th May 2023

Subject Device Information:

Trade name: Somfit
Common name: Somfit
Product code: MNR, OMC
Classification Names: Ventilatory Effort Recorder
Panel: Anesthesiology
Device class: II
Regulation number: 21 CFR 868.2375

Predicate Device Information

Trade Name: Watch-PAT300
Manufacturer: Itamar Medical, Ltd.
510(k) number: K180775
510(k) Decision Date: 17th August 2018
Classification: Ventilatory Effort Recorder
Product code: MNR
Device class: II
Regulation number: 21 CFR 868.2375

Reference Device(s) Information

Trade Name:	NightOwl
Manufacturer:	Ectosense
510(k) number:	K191031
510(k) Decision Date:	6th March 2020
Classification:	Ventilatory Effort Recorder
Product code:	MNR
Device class:	II
Regulation numbers:	21 CFR 868.2375

Trade Name:	X4 System
Manufacturer:	Advanced Brain Monitoring
510(k) number:	K130013
510(k) Decision Date:	31st January 2013
Classification:	Reduced-Montage Standard Electroencephalograph
Product code:	OMC
Device class:	II
Regulation numbers:	21 CFR 882.1400

Trade Name:	SomnaPatch
Manufacturer:	Respironics Inc
510(k) number:	K183625
510(k) Decision Date:	18th October 2019
Classification:	Ventilatory Effort Recorder
Product code:	MNR
Device class:	II
Regulation numbers:	21 CFR 868.2375

Device Description

The Somfit is a home-based sleep monitoring device which records signals from the patient's forehead and surrounding environment. Somfit is a wearable, low voltage, battery operated device which is attached to subject forehead via a self-adhesive and disposable skin electrode patch. The electrodes are placed on the anterior Prefrontal cortex (PFC) at the Fp1 and Fp2 positions according to the 10/20 EEG system. The device allows for recording of two frontal EEG signals, pulse rate, SPO2, Peripheral Arterial Tonometry (PAT), PPG, motion, and snore. Somfit uses a mobile phone application to acquire data wirelessly via Bluetooth LE technology, then transfer into a secure cloud, for management, storage and post-processing. The software reports measured parameters in a format compatible with AASM guidelines, including sleep time, pAHI and conventional graphical displays such as a hypnogram.

Intended Use / Indications For Use

The ***Somfit*** system is a non-invasive prescription device for home use with patients suspected to have sleep-related breathing disorders. The ***Somfit*** is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. The ***Somfit*** system acquires electrical data from three frontal electrodes, tri-axial accelerometer data, acoustic and plethysmographic data. The ***Somfit*** calculates and reports to clinicians EEG/EOG channels, Sleep Stages, $SpO2$, Peripheral Arterial Tonometry (PAT) signal, pulse rate, and snoring level. The Somfit calculates and reports to clinicians derived parameters such as PAT-derived Apnea Hypopnea Index, Obstructive Desaturation Index; and hypnogram-derived indices such as time in each sleep stage. ***Somfit*** data is not intended to be used as the sole or primary basis for diagnosing any sleep-related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. The ***Somfit*** is not intended for use as life support equipment, for example vital signs monitoring in intensive care unit. The ***Somfit*** is a prescription device indicated for adult patients aged 21 years and over.

Comparison of Intended Use

The Somfit has the same intended use as the Watch-PAT300 as a Home Sleep Apnea Test device. The Somfit is intended only for adults, which narrows the indications for use. Somfit does not make clinical claims of distinguishing obstructive and central apnea, which conventionally is performed through direct measurement of airflow (such as nasal cannula) and respiratory effort (such as abdominal inductive belt).

Comparison of Technological Characteristics

The Somfit uses the same fundamental technology and principles of operation as the Watch-PAT300. Both devices are low power battery-operated ventilatory effort recorders utilizing oximeters, tri-axial accelerometers, microphone, and PAT-based technology. The Somfit is notably worn on forehead as opposed to the wrist, and uses an EEG sensor to directly measure brain activity and determine sleep stage. The Somfit data is acquired using a mobile application which uploads data to the Nexus360 Web Server for automatic analysis and review by physician. This workflow is slightly different to the Watch-PAT300 which uses a push button interface, and stores study data in flash memory until a USB connection to a PC running zzzPAT software is made, and upload to the CloudPAT server is manually initiated. Further analysis of technological characteristics is available in the Substantial Equivalence discussion. The Somfit uses the same underlying principles of operation as the Watch-PAT300, and design differences do not raise questions of safety or effectiveness.

Reference has been made to the X4 System in regards to the use of EEG as opposed to actigraphy for sleep staging. Reference has been made to the SomnaPatch for its use of reflectance oximetry at the forehead location. Reference has additionally been made to the NightOwl in regards to test methods used for the validation of PAT and PAT-derived AHI.

Use of Reference Devices

In addition to the predicate Watch-PAT300, reference has been made to similar sleep assessment devices to assist in the determination of substantial equivalence, in accordance with FDA Guidance Documentation.

The use of a forehead-based reflectance oximeter by Somfit in comparison to a finger transmittance oximeter was noted as a technological difference by the FDA. The SomnaPatch (K183625) was leveraged as a reference device as it also uses forehead reflectance oximeter technology like Somfit. A tabular comparison and further technical discussion was provided to the FDA. Reference was additionally made to the SomnaPatch regarding the use of a functional simulator for verification and validation of the associated pulse rate channel.

The use of EEG technology for the determination of sleep stage as opposed to actigraphy used by Watch-PAT300 has been noted as a technological difference by the FDA. We believe that this does not raise questions of safety and effectiveness since direct measurement of brain activity through EEG is considered by the American Academy of Sleep Medicine to be preferable to actigraphy, and have provided discussion to that effect in document. However, regardless we leveraged the X4 System (K130013) as a reference device. The X4 System is one of several marketed devices which similarly records EEG/EOG at frontal locations for review by physicians with automatic analysis software (separately cleared as Sleep Profiler). This is fundamentally the same technology utilized by Somfit. Further technical discussion and comparison of devices was provided to the FDA.

The peripheral arterial tonometry (PAT) signal is derived directly from the PPG, where changes in morphology such as relative reduction in amplitude are indicative of sympathetic activity in response to respiratory events. There is no standardized methodology for calculation of PAT, and numerical values of the PAT signal are expected to differ based on electronic characteristics of the acquisition hardware, and other described factors. The primary methodology used by Somfit to validate the PAT channel is comparison of the PAT-derived apnea hypopnea index with that of the predicate device, and gold standard AHI as measured by Polysomnography. Reference was made to the NightOwl device (K191031) which reported the same methods for validation of their PAT channel. Further discussion of test methodology and comparison of devices was provided to the FDA.

Non-Clinical Performance Data

Testing activities were conducted as part of this submission to verify that the Somfit does not raise any issues of safety and effectiveness, and to verify implementation of risk controls. These included:

- Electrical Safety Testing as per IEC 60601-1:2005 (Third Edition) + COR1:2006 + COR2:2007 + A1:2012
- Electromagnetic Compatibility Testing as per IEC 60601-1-2:2014, EN 60601-1-2:2015, and modification by the listed particular and collateral standards
- Home Healthcare Environmental testing as per IEC 60601-1-11:2015
- Electroencephalograph safety and performance testing as per IEC 60601-2-26:2012
- Pulse oximeter safety and performance testing as per ISO 80601-2-61:2011 including tests with functional simulator

- Hardware bench testing to verify electrical parameters and design specifications
- Software testing to verify functional requirements and system integration

Further test details are available in this submission. All tests passed, demonstrated substantial equivalence, and did not raise additional concerns of safety and effectiveness. The test methods are in line with international standards where they exist, and other FDA-cleared devices where outputs have not yet been standardized.

Clinical Performance

Multiple clinical studies were conducted to provide clinical validation of Somfit performance. Detailed results and analysis are available in the substantial equivalence discussion, and clinical volume.

A formal controlled desaturation study was conducted in accordance with ISO 80601-2-61 at Hypoxia Lab. This involved comparison between Somfit SpO_2 data and gold standard SaO_2 data over an invasively controlled SaO_2 range of 70%-100%. The Somfit root mean square error (A_{RMS}) was 1.46%, out-performing Nonin and Masimo reference devices used during the study, which reported 2.15% and 1.94% respectively. The Watch-PAT300 user guide reports an A_{RMS} of 1.88% based on results from its own controlled desaturation study. The Somfit's A_{RMS} of 1.46% for the same SaO_2 range is less, supporting the claim of substantial equivalence, and satisfying performance requirements of ISO 80601-2-61.

Pulse rate data was obtained from Nonin and Masimo reference oximeters during a controlled desaturation study. Two hundred and thirty-seven pulse rate samples were obtained from 12 healthy patients, and analysed using the statistical methods mandated by ISO 80601-2-61. The root-mean square error was found to be 1.91 BPM with a mean difference of 0.017 BPM between the Somfit and Masimo oximeters. The root-mean square error was found to be 1.81 BPM with a mean difference of 0.00 BPM between the Somfit and Nellcor oximeters. Potential sources of error may include inadequate synchronization between devices, since oximeters provide a range of data update rates, and were placed at differing anatomical locations, as well as additional patient motion associated with the condition of profound hypoxemia during wake. In addition to testing against a pulse rate simulator, this clinical performance data supports the claim of substantial equivalence and satisfies validation requirements of ISO 80601-2-61.

A clinical study was conducted to obtain clinical data for the purpose of comparing Somfit and Watch-PAT300. A study protocol was reviewed and approved by an Independent Ethics Committee with predefined hypotheses, study population, endpoints, and analysis techniques. In total 92 subjects were recorded across 3 site locations in Australia. All subjects had Somfit and Watch-PAT300 recording overnight data while undergoing attended polysomnography using the Grael device, which is the gold standard technology to assist in the diagnosis of sleep disorders. Watch-PAT300 and Somfit measured parameters such as PAT-derived AHI (pAHI) and sleep stage concordance were evaluated, and directly compared to each other, and the established ground truth.

Somfit and Watch-PAT300 PAT-derived AHI had a mean difference of 0.294 with 95 percent confidence interval of -2.661, 2.074, which was within the predetermined margin supporting the non-inferiority hypothesis. The mean difference of Somfit and PSG ODI of 0.658 with confidence interval of -1.012, 2.326 was less than the mean difference of Watch-PAT300 and PSG ODI of 2.499 with confidence interval of 0.732,

4.265, indicating Somfit achieved higher accuracy with respect to the gold standard. Somfit had an 80.92% agreement (95 percent CI: 79.96, 81.89) for N1/N2 merged sleep stages compared to Watch-PAT300 61.77% (95 percent CI: 60.99, 62.55). Somfit had a 86.79% agreement (95 percent CI: 85.76, 87.81) for NREM/REM/Wake stage differential compared to Watch-PAT300 of 74.42% agreement (95 percent CI: 73.51, 75.32). Somfit had an 89.45% agreement (95 percent CI: 88.53, 90.38) with PSG for sleep/wake determination compared to Watch-PAT300 of 82.09% (95 percent CI: 81.37, 82.82).

The sleep staging confusion matrix for agreement between Somfit and PSG is presented in table 1. The PSG epochs were classified based on the consensus of three scoring sleep technologists.

		Somfit				
		Wake	**N1**	**N2**	**N3**	**REM**
PSG	**Wake**	16773	981	1579	142	1480
	N1	2123	1335	2502	27	799
	N2	2007	1337	29089	836	782
	N3	166	34	4206	8224	11
	REM	700	89	611	17	11157

Table 1: Confusion Matrix between the Somfit and PSG sleep staging

The calculated sensitivities of sleep stages and combinations of sleep stages are presented in table 2, including the number of epochs used for each calculation.

Stage detection Sensitivities	Somfit (No. PSG epochs)	WatchPAT (No. PSG epochs)
Pr(Wake|PSG Wake)	0.8004, (20955)	0.3497, (20909)
Pr(N1|PSG N1)	0.1967, (6789)	N/A, (6770)
Pr(N2|PSG N2)	0.8540, (34051)	N/A, (34006)
Pr(N3|PSG N3)	0.6509 ,(12641)	0.4799, (12641)
Pr(REM|PSG REM)	0.8873, (12574)	0.7219, (12555)
Pr(N1+N2|PSG N1+N2)	0.8388 ,(40840)	0.7662, (40776)
Pr(NREM|PSG NREM)	0.8897, (53481)	0.9042, (53417)
Pr(Sleep|PSG Sleep)	0.9244, (66055)	0.9706, (65972)

Table 2. Sensitivities for different sleep stages and combinations of sleep stages.

The estimates of differences in the percent agreement between Watch-PAT300 and PSG consensus versus the percent agreement between Somfit and PSG consensus for the three sets of sleep staging categories are presented in table 3.

	Point estimate, %	95% Confidence Interval	97.5% Confidence Interval
N1, N2 merged	-19.23	[-22.57; -15.89]	[-23.07; -15.39]
NREM/REM/Wake	-12.49	[-15.97; -8.99]	[-16.49; -8.49]
Sleep/Wake	-7.45	[-10.89; -4.03]	[-11.37; -3.53]

Table 3: Estimates of the difference in sleep staging percent agreement between Somfit and PSG consensus, and between Watch-PAT and PSG consensus using non-parametric bootstrap sampling.

A detailed comparison is provided through evaluation of design features such as energy source, principles of operation, materials, and user interface. Further comparison and analysis is available in VOL_012_Substantial Equivalence Discussion.

	Predicate Device Watch-PAT300 (K180775)	New Device Somfit
Manufacturer	Itamar Medical Ltd	Compumedics Limited
Device Classification	MNR	MNR, OMC
FDA Classification	Class II	Class II
Indications for Use	The Watch-PAT300 (WP300) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP300 is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP300 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP300's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP300's PSTAGES and snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older	The ***Somfit*** system is a non-invasive prescription device for home use with patients suspected to have sleep-related breathing disorders. The ***Somfit*** is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. The ***Somfit*** system acquires electrical data from three frontal electrodes, tri-axial accelerometer data, acoustical and plethysmographic data. The ***Somfit*** calculates and reports to clinicians EEG/EOG channels, Sleep Stages, *SpO*2, Peripheral Arterial Tonometry (PAT) signal, pulse rate, and snoring level. The Somfit calculates and reports to clinicians derived parameters such as PAT-derived Apnea Hypopnea Index, Obstructive Desaturation Index; and hypnogram-derived indices such as time in each sleep stage. ***Somfit*** data is not intended to be used as the sole or primary basis for diagnosing any sleep-related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. The ***Somfit*** is not intended for use as life support equipment, for example vital signs monitoring in intensive care unit. The ***Somfit*** is a prescription device indicated for adult patients aged 21 years and over.
Type of Use	Prescription Use Only	Prescription Use Only
Patient population	12 years and above, with some features 17 years and above	Adults – 21 years and above
Usage Environment	Home	Home
Mass	98g (excluding uPAT probe weight of 20g)	≤ 15g (with battery)
Dimensions	69mm x 59mm x 17mm	43mm x 43 mm x 19.7 mm (device + charging cradle)
Biocompatibility	Overnight use on intact skin	Overnight use on intact skin
Materials	Plastic Bracelet (unspecified)	Adhesive (wet) electrode ABS Plastic
Sold Sterile or Sterilization Required	No	No
Energy Source	One OTS 1.5V Alkaline AAA battery OR one rechargeable AAA 1.2V Nickel-metal hydride (NiMH) rechargeable battery > 700mAh	1 x 120mAh 3.7V Li-Ion battery
Battery Life	Approximately 10 hours	Hours of Use: On standby/idle mode: 48 hours (2 days)

		Recording: 16 hours continuous recording
Microprocessor	ARM (Nordic)	ARM (TI)
Electronic Sensors	Photodiode Oximeter front end (AFE4404) Microphone Accelerometer	Photodiode Oximeter front end (AFE4404) Microphone Accelerometer EEG Amplification
Channel	PAT Pulse Rate Oximetry Actigraphy Snoring (Optional) Body Position (Optional) Chest Movement (Optional)	PAT Pulse Rate Oximetry EEG Snoring Motion
Analysis Output	pRDI pAHI pAHIc ODI Sleep stages Snoring level (optional) Body Position discrete states (Optional)	pAHI Sleep stages Snoring Level ODI
Application Site	Main device on wrist with finger probe.	Forehead
Device Visual Indicator	OLED screen	Green and blue LEDs on device, mobile application
User Control	Device push buttons	Start/stop button on mobile application
Data Collection	Study data is saved on device flash memory then transferred to PC via USB cable. Data can be accessed by zzzPAT software and uploaded to CloudPAT web server.	Study data is wirelessly transferred through Bluetooth from the device to a mobile application. Data is then uploaded to Nexus360 web server for storage and analysis.

Table 4: Comparison of Technological Characteristics

Conclusion

Compumedics Ltd. considers the Somfit to be substantially equivalent to its predicate device the Watch-PAT300. The intended use as an HSAT device are identical. The fundamental principles of operation are the same, and where differences exist they have been discussed. There are no questions of safety and effectiveness, and substantial equivalence is supported by extensive performance testing and clinical data.