



Shenzhen Beacon Display Technology Co., Ltd.  
% Miss Fu Ailing  
Document Engineer  
12F, Block B1, Nanshan Zhiyuan, No.1001 Xueyuan Road  
Shenzhen, Guangdong 518055  
CHINA

May 19, 2020

Re: K200864

Trade/Device Name: 5MP Color LCD Monitors C53S+, C53SP+, 5MP Monochrome LCD  
Monitors G53S+, G53SP+

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: Class II

Product Code: PGY

Dated: March 10, 2020

Received: April 1, 2020

Dear Miss Ailing:

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); 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## 510(k) Summary

[As required by 21 CFR 807.92]

### 1. Date Prepared [21 CFR807.92 (a) (1)]

March 10, 2020

### 2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: Shenzhen Beacon Display Technology Co., Ltd.

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### 3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name/Model: 5MP Color LCD Monitors C53S+, C53SP+;

5MP Monochrome LCD Monitors G53S+, G53SP+

Common Name: 5MP LCD Monitors C53S+, C53SP+, G53S+, G53SP+

Classification Name: Picture archiving and communications system

Regulation Number: 21 CFR 892.2050

Product code: PGY

Classification Panel: Radiology

Device Class: II

### 4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate within this submission is as follows:

JVC Kenwood Corporation, 5MP Color LCD Monitor CL-S500, 5MP Monochrome LCD Monitor MS-S500 has been cleared by FDA through 510(k) No. K191137 (Decision Date - July 2, 2019).

## **5. Description of the Device [21 CFR 807.92(a) (4)]**

5MP LCD Monitors C53S+, C53SP+, G53S+, G53SP+ are 21.3-inch TFT LCD monitors, which are specifically designed to provide the high definition image output for general radiography.

These products have been strictly calibrated so that they can meet DICOM Part 3.14 and other standards. They use the latest generation of LED backlight panel, supporting resolution 2048 x 2560. The built-in brightness stabilization control circuit makes sure the brightness of these monitors is stable in their lives and the calibration is continuous, so these products meet the demand of high precision medical imaging. For C53SP+ and G53SP+ surface protection panels with anti-reflection coating, there are characteristics such as anti-reflection, easy cleaning and anti-scratch screen.

Model variations are distinguished by characters. C means the Color monitor, G means the Monochrome monitor, and P means the monitor with an additional glass screen. For example, C53S+ is a color LCD monitor; G53SP+ is a monochrome LCD monitor with the additional glass screen.

## **6. Intended Use [21 CFR 807.92(a)(5)]**

The 5MP Color LCD Monitors C53S+, C53SP+ and 5MP Monochrome LCD Monitors G53S+, G53SP+ are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

## **7. Technological Characteristics [21 CFR 807.92(a)(6)]**

**C53S+, C53SP+ Color LCD monitors**

<b>Monitor characteristics :</b>	
Screen technology	21.3", TFT, color, LCD screen, anti-glare, hard coating
Active area( H x V)	337.92 x 422.4 mm
Pixel pitch	0.165 mm (H) x 0.165 mm (V)
Resolution	2048 x 2560
Contrast ratio	2000:1 (typical), 1600:1 (min.)
Viewing angle ( CR > 10 )	Horizontal: 178° (typ.)
	Vertical: 178° (typ.)
Screen brightness	1150 cd/m <sup>2</sup> (typ.)
Refresh rate	50 Hz
Backlighting	LEDs
Lifetime of backlight	50000 hours
Response time ( Ton + Toff )	25 ms (typ.)
<b>Power supply :</b>	
Line voltage	12 V
Current consumption	6.67 A
Power consumption	80 W (max.)
Standby	< 5 W
<b>Control and connection :</b>	
Front	1 operation LED, 6 functional keys
Back	<ul style="list-style-type: none"> <li>• Ground*1</li> <li>• Power switch*1</li> <li>• DVI-D*1</li> <li>• DP*1</li> <li>• RJ45*1</li> <li>• USB Upstream Port*1</li> <li>• USB Downstream Port*2</li> </ul>

<b>Mechanical characteristics :</b>	
Housing components	Plastic+Metal
Ventilation openings	Natural heat radiation
Protection level	IP 20 IP 65 (Applicable to the front panel of C53SP+)
<b>Climatic conditions :</b>	
Working temperature	0°C - 40°C
Working humidity	15% - 85% Relative humidity, no condensation
Working atmospheric pressure	700 hPa - 1060 hPa
Transport and storage temperature	-20°C - 60°C
Transport and storage humidity	10% - 90% Relative humidity, no condensation
Transport and storage atmospheric pressure	700 hPa - 1060 hPa
<b>Safety regulations :</b>	
Safety standards	IEC60601-1, EN60601-1 ANSI/AAMI ES60601-1: 2005 + A2(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1:14
Conformity	CCC, CE, TUV, FCC
<b>Dimension:</b>	
Dimensions (W x H x D) in mm	395.3 x 549.6 ~ 629.6 x 234.8 mm
With packing (W x H x D)	608 x 561 x 327 mm
<b>Weight :</b>	
Net weight	9.5 ± 0.5 kg
Gross weight	13.0 ± 0.5 kg

**G53S+, G53SP+ Monochrome LCD monitors**

<b>Monitor characteristics :</b>	
Screen technology	21.3", TFT, grayscale, LCD screen, anti-glare, hard coating
Active area( H x V)	337.92 x 422.4 mm
Pixel pitch	0.165 mm (H) x 0.165 mm (V)
Resolution	2048 X 2560
Contrast ratio	2000:1 (typ.), 1600:1 (min.)
Viewing angle ( CR > 10 )	Horizontal: 178° (typ.)
	Vertical: 178° (typ.)
Screen brightness	3000 cd/m <sup>2</sup> (typ.)
Refresh rate	50 Hz
Backlighting	LEDs
Lifetime of backlight	50000 hours
Response time ( Ton + Toff )	25 ms (typ.)
<b>Power supply :</b>	
Line voltage	12 V
Current consumption	6.67 A
Power consumption	80 W (max.)
Standby	< 5 W
<b>Control and connection :</b>	
Front	1 operation LED, 6 functional keys
Back	<ul style="list-style-type: none"> <li>• Ground*1</li> <li>• Power switch*1</li> <li>• DVI-D*1</li> <li>• DP*1</li> <li>• RJ45*1</li> <li>• USB Upstream Port*1</li> <li>• USB Downstream Port*2</li> </ul>

<b>Mechanical characteristics :</b>	
Housing components	Plastic+Metal
Ventilation openings	Natural heat radiation
Protection level	IP 20 IP 65 (Applicable to the front panel of G53SP+)
<b>Climatic conditions :</b>	
Working temperature	0°C - 40°C
Working humidity	15% - 85% Relative humidity, no condensation
Working atmospheric pressure	700 hPa - 1060 hPa
Transport and storage temperature	-20°C - 60°C
Transport and storage humidity	10% - 90% Relative humidity, no condensation
Transport and storage atmospheric pressure	700 hPa - 1060 hPa
<b>Safety regulations :</b>	
Safety standards	IEC60601-1, EN60601-1 ANSI/AAMI ES60601-1: 2005 + A2(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1:14
Conformity	CCC, CE, TUV, FCC
<b>Dimension:</b>	
Dimensions (W x H x D) in mm	395.3 x 549.6 ~ 629.6 x 234.8 mm
With packing (W x H x D)	608 x 561 x 327 mm
<b>Weight :</b>	
Net weight	9.5 ± 0.5 kg
Gross weight	13.0 ± 0.5 kg



## 8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

### 8.1 Intended uses:

**Table 1 Intended Use Comparison of C53S+, C53SP+, G53S+, G53SP+**

ID	Comparison Item	<b>Proposed Device</b> <b>5MP Color LCD Monitors C53S+, C53SP+;</b> <b>5MP Monochrome LCD Monitors G53S+,</b> <b>G53SP+</b>	<b>Predicate Device</b> <b>5MP Color LCD Monitor CL-S500, 5MP</b> <b>Monochrome LCD Monitor MS-S500</b>
1	<b>Intended Use</b>	The 5MP Color LCD Monitors C53S+, C53SP+ and 5MP Monochrome LCD Monitors G53S+, G53SP+ are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	CL-S500 and MS-S500 are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

### 8.2 Comparison table

**Table 2 General Comparison of C53S+, C53SP+**

<b>ID</b>	<b>Comparison Item</b>	<b>Proposed Device 5MP Color LCD Monitors C53S+, C53SP+</b>	<b>Predicate Device 5MP Color LCD Monitor CL-S500</b>	<b>Explanation of Differences</b>
<b>2</b>	<b>Display Performance/Specifications</b>			
<b>2.1</b>	<b>Screen Technology</b>	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
<b>2.2</b>	<b>Viewing angle (H, V)</b>	CR>10 Horizontal: Typ.178 Vertical: Typ.178	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Different screen provided by the different manufacturer
<b>2.3</b>	<b>Resolution or matrix size</b>	5MP(2048 X 2560)	5MP(2048 X 2560)	-
<b>2.4</b>	<b>Aspect ratio</b>	4:5	4:5	-
<b>2.5</b>	<b>Display area</b>	Horizontal: 337.92mm Vertical: 422.4mm	Horizontal: 337.92mm Vertical: 422.4mm	-
<b>2.6</b>	<b>Pixel pitch</b>	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
<b>2.7</b>	<b>Response time (Typ.)</b>	25ms (On/Off)	25ms (On/Off)	-
<b>2.8</b>	<b>Maximum luminance</b>	Min. 920cd/m <sup>2</sup> Typ. 1,150cd/m <sup>2</sup>	Min. 920cd/m <sup>2</sup> Typ. 1,150cd/m <sup>2</sup>	-
<b>2.9</b>	<b>DICOM calibrated luminance</b>	500cd/m <sup>2</sup>	500cd/m <sup>2</sup>	-

2.10	<b>Contrast ratio</b>	Min. 1600:1 Typ. 2000:1	Min. 1600:1 Typ. 2000:1	-
2.11	<b>Backlighting</b>	LED	LED	-
2.12	<b>Grayscale Tones</b>	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,369 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,369 tones	Tone between the predicate device and our proposed devices are different. But they pass the exams in AAPM-TG18 4.3 “Luminance Response” . Therefore, they are equivalent to the predicate device.
2.13	<b>Luminance non-uniformity compensation</b>	-	Digital Uniformity Correction System	Different design scheme
3	<b>Video Signals</b>			
3.1	<b>Input video signals</b>	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-
3.2	<b>Scanning Frequency (H, V)</b>	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Portrait: Horizontal: 129.1KHz Vertical: 50Hz Landscape: Horizontal: 103.5KHz Vertical: 50Hz	-
3.3	<b>Dot Clock</b>	285 MHz	285 MHz	-

4	<b>Power Related Specifications</b>			
4.1	<b>Power Requirements</b>	DC 12V, 6.67A	AC 100-240V, 50/60Hz	Difference between built-in power supply and built-out power supply
4.2	<b>Power Consumption / Save Mode</b>	80W Less than 5W	95W Less than 1W	Compared with the predicate device, the proposed device consumes less power in the operating mode and more power in the power saving mode.
4.3	<b>Power Management</b>	DVI DPMS, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2a	Different design scheme
5	<b>Miscellaneous Features/Specifications</b>			
5.1	<b>QC software</b>	Beacon Monitor Manage	QA Medivisor / Medivisor NXF-CAL	Different design scheme
5.2	<b>Sensors</b>	Built-in Front Sensor (only for C53SP+) Built-in Ambient Light Sensor Built-in Backlight Sensor	Built-in Front Sensor Built-in Ambient Light Sensor	Different design scheme
5.3	<b>USB Ports/Standard</b>	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
5.4	<b>Dimensions w/o stand (W x H x D)</b>	395.3 x 549.6/629.6 x 234.8 mm	361.5 x 517/612 x 196.5 mm	Different housing design due to the different panel size

**Table 3 General Comparison of G53S+/G53SP+**

ID	Comparison Item	Proposed Device 5MP Monochrome LCD Monitors G53S+, G53SP+	Predicate Device 5MP Monochrome LCD Monitor MS-S500	Explanation of Differences
2	<b>Display Performance/Specifications</b>			
2.1	<b>Screen Technology</b>	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
2.2	<b>Viewing angle (H, V)</b>	CR>10 Horizontal: Typ.178 Vertical: Typ.178	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Different screen provided by the different manufacturer
2.3	<b>Resolution or matrix size</b>	5MP(2048 X 2560)	5MP(2048 X 2560)	-
2.4	<b>Aspect ratio</b>	4:5	4:5	-
2.5	<b>Display Area</b>	Horizontal: 337.92mm Vertical: 422.4mm	Horizontal: 337.92mm Vertical: 422.4mm	-
2.6	<b>Pixel pitch</b>	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
2.7	<b>Response Time (Typ.)</b>	25ms (On/Off)	25ms (On/Off)	-
2.8	<b>Maximum luminance</b>	Min. 2,400cd/m <sup>2</sup> Typ. 3,000cd/m <sup>2</sup>	Min. 2,400cd/m <sup>2</sup> Typ. 3,000cd/m <sup>2</sup>	-

2.9	<b>DICOM calibrated luminance</b>	500cd/m <sup>2</sup>	1,000cd/m <sup>2</sup>	The luminance ratio (max/min) between 250 and 650 generally recommended taking account of the contrast sensitivity of human eyes is available in the proposed devices. Beacon does not see merits of the extremely high luminance offering contrast beyond what the eyes can see.
2.10	<b>Contrast ratio</b>	Min. 1600:1 Typ. 2000:1	Min. 1600:1 Typ. 2000:1	-
2.11	<b>Backlighting</b>	LED	LED	-
2.12	<b>Grayscale Tones</b>	10-bit (DisplayPort): 1,024 from a palette of 16,384 tones 8-bit (DVI): 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit (DVI): 256 from a palette of 16,369 tones	Tone between the predicate device and our proposed devices are different. But they pass the exams in AAPM-TG18 4.3 “Luminance Response” . Therefore, they are equivalent to the predicate device.
2.13	<b>Luminance non-uniformity compensation</b>	-	Digital Uniformity Correction System	Different design scheme
3	<b>Video Signals</b>			
3.1	<b>Input video signals</b>	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-

3.2	<b>Scanning Frequency (H, V)</b>	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Portrait: Horizontal: 129.1KHz Vertical: 50Hz Landscape: Horizontal: 103.5KHz Vertical: 50Hz	-
3.3	<b>Dot Clock</b>	285 MHz	285 MHz	-
4	<b>Power Related Specifications</b>			
4.1	<b>Power Requirements</b>	DC 12V, 6.67A	AC 100-240V, 50/60Hz	Difference between built-in power supply and built-out power supply
4.2	<b>Power Consumption / Save Mode</b>	80W Less than 5W	80W Less than 1W	Compared with the predicate device, the proposed device consumes more power in the power saving mode.
4.3	<b>Power Management</b>	DVI DPMS, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2a	Different design scheme
5	<b>Miscellaneous Features/Specifications</b>			
5.1	<b>QC software</b>	Beacon Monitor Manage	QA Medivisor / Medivisor NXF-CAL	Different design scheme
5.2	<b>Sensors</b>	Built-in Front Sensor (only for G53SP+) Built-in Ambient Light Sensor Built-in backlight sensor	Built-in Front Sensor Built-in Ambient Light Sensor	Different design scheme

<b>5.3</b>	<b>USB Ports/Standard</b>	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
<b>5.4</b>	<b>Dimensions w/o stand (W x H x D)</b>	395.3 x 549.6/ 629.6 x 234.8 mm	361.5 x 517/612 x 196.5 mm	Different housing design due to the different panel size



It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the C53S+, C53SP+, G53S+, G53SP+.

### 8.3 Performance Testing

The bench tests were performed on C53S+, C53SP+, G53S+, G53SP+ as below.

- Verify the conformance to DICOM GSDF in accordance with *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline).
- Measure the calibrated luminance according to the requirements of the “Luminance Response” test in TG18 guideline.
- Measure the luminance non-uniformity characteristics of the display screen in accordance with TG18 guideline.
- Measure the luminance stability and chromaticity response with the temperature 0°C, 25°C and 40°C on Luminance response by AAPM-TG18.
- Measure the chromaticity non-uniformity characteristics of the display screen in accordance with TG18 guideline.
- Measure the luminance at the angles of 30° and 45° in diagonal, horizontal and vertical directions at center and four corners by AAPM-TG18.
- Measure the temporal response using the typical data provided by the panel manufacturer.
- Visually check the presence or absence of miscellaneous artifacts on the display screen in accordance with TG18 guideline.
- Measure the spatial noise by noise power spectrum.
- Measure the reflection coefficient with specular reflection and diffuse reflection by TG18.
- Measure the veiling glare of small-spot contrast performing veiling glare test by TG-18.
- Measure the spatial resolution expressed as modulation transfer function (MTF)
- Maximum number allowed for each type of pixel defects/faults
- Measure pixel fill factor like pixel structure and aperture ratio etc.

The test results showed that C53S+, C53SP+, G53S+, G53SP+ are with display characteristics equivalent to those of the predicate devices, MS-S500, CL-S500 except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for C53S+, C53SP+, G53S+, G53SP+.

## **9. Conclusion [21 CFR 807.92(b) (3)]**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shenzhen Beacon Display Technology Co., Ltd. concludes that:

- The intended use of C53S+, C53SP+, G53S+, G53SP+ is totally same as that of the predicate devices.
- The technological characteristics differences between C53S+, C53SP+, G53S+, G53SP+ and the predicate devices do not affect the safety and effectiveness, so no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of C53S+, C53SP+, G53S+, G53SP+ are equivalent to those of the predicate devices.

## **006\_Indications for Use Statement**

## Indications for Use

510(k) Number (if known)  
K200864

Device Name

5MP Color LCD Monitors C53S+, C53SP+; 5MP Monochrome LCD Monitors G53S+, G53SP+

Indications for Use (Describe)

The 5MP Color LCD Monitors C53S+, C53SP+ and 5MP Monochrome LCD Monitors G53S+, G53SP+ are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

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)

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