January 30, 2018

Intromedic Co., Ltd.
Jinyoung Lee
General Manager
Suite 1105, 1106, E&C Venture Dream Tower 6-Cha
Guro-dong, Guro-gu
Seoul, 08375
Korea

Re: K170438
Trade/Device Name: MiroCam® Capsule Endoscope System
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: II
Product Code: NEZ
Dated: December 7, 2017
Received: December 14, 2017

Dear Jinyoung Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170438

Device Name
MiroCam® Capsule Endoscope System

Indications for Use *(Describe)*
The MiroCam® Capsule Endoscope System is intended for visualization of the small bowel mucosa.

- It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy.

It may be used as a tool in the detection of abnormalities of the small bowel and this device is indicated for adults only.

The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.

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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5. 510(k) Summary

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

1. Company and Correspondent making the submission

Name	IntroMedic Co., Ltd.
Address	Suite 1105, 1106, E&C Venture Dream Tower 6-Cha, 197-28 Guro-dong, Guro-gu, Seoul, 08375, Korea
Telephone	+82-2-801-9300
Fax	+82-2-801-9330
Contact	Jinyoung Lee
Internet	http://www.intromedic.com

2. Device

Proprietary Name	MiroCam® Capsule Endoscope System
Common Name	Capsule Imaging System
Classification Name	21 CFR 876.1300 (Product Code NEZ) Ingestible telemetric gastrointestinal capsule imaging system

3. Predicate Device

Manufacturer	IntroMedic Co., Ltd.
Device	MiroCam® Capsule Endoscope System
510(K) Number	K143663
Manufacturer	Given Imaging Ltd.
Device	Given PillCam SB3 Capsule endoscopy system
510(K) Number	K123864
Manufacturer	Given Imaging Ltd.
Device	Given PillCam COLON 2 Capsule endoscopy system
510(K) Number	K123666 (Reference device)

4. Description

The MiroCam® Capsule Endoscope System is comprised of the following core components:

- MiroCam® Capsule: MC2000-B
- MiroCam® Receiver: MR2000
- Data Cable / Data Belt (Optional): MR1000-D / MR1000-D(S) or MR1000-D(M) or MR1000-D(L)
- MiroView™ Software: MiroView™ U 4.0

The general usage workflow of the MiroCam® system is as follows, the MiroCam® capsule captures images of the GI tract, which are sent via Human Body Communication to sensor pads which are affixed to the patient body. The sensor pads are connected to the receiver by the data cables. The image data is stored on the receiver for the duration of the patient procedure. After removing the receiver set from the patient body, the receiver is connected via USB to the Commercial PC and the image data is uploaded. Following upload, the physician (Gastroenterologist) reviews the patient image data for suspected abnormalities of the small bowel. The key system components are explained in detail below.

MiroCam® Capsule

Functionally, the MiroCam® capsule captures imaging via a CMOS imaging sensor for at least 12 hours at the rate of 6 images per second. Twelve white LEDs flash in concert with the imaging sensor. A sensor PCB links the imaging sensor to the two gold electrodes of the capsule, from which a weak current is emitted containing the image data via Human Body Communication technology. The weak current is then passed through the bodily tissue and fluid to be picked up by the sensor pads. Human Body Communications is uni-directional from the capsule to the sensor pads.

Physically, the capsule is 30.1mm in length, and 10.8mm in diameter. The exterior of the capsule is composed of biocompatible materials, capable of withstanding potential bite forces and exposure to fluids in the GI tract.

MiroCam® Receiver

The image data from the capsule is saved to the MiroCam® Receiver via the sensor pads and data cables. The sensor pads are standard ECG type sensor pads (3M Red Dot), which are affixed to the patient's abdomen according to the location guide. The 9 sensor pads are attached to the 9 leads of the data cable, and the data cable is subsequently attached to the Receiver. The Receiver sits in a shoulder pouch, which is put on the patient for the duration of the procedure. A waist pouch is used to organize the data cables.

The Receiver can store images for up to 12 hours. Using LCD display it shows icons that indicate the state of receiver, real time image view and preview. User can capture image for the real time images are displayed. Three LEDs also represent the receiver state by switching its power. And MiroCam® receiver play some sounds for notifying to user. To reduce the battery consumption of MiroCam® receiver backlight brightness is controlled. User can control MiroCam® receiver by using three buttons.

The dimensions of the receiver are 145mm in height, 82.5mm in width, and 29.8mm in length. The units weight 330 grams, which is data cable. The battery is lithium ion, and is unique to the Receiver. The battery is rechargeable, and can be charged by placing in the battery charger provided with the Receiver. The receiver uses a storage flash for storing the images.

MiroView™ U 4.0

The MiroView™ U 4.0 helps the user to upload the image data from the Receiver and review the image data with displaying.

MiroView™ U 4.0 will be deployed as three types of software: MiroView™ Server, MiroView™ Operator and MiroView™ Client.
Server PC includes two types of S/W: MiroView™ Server and Operator.

MiroView™ Server and MiroView™ Operator will be deployed on a Server PC. MiroView™ Client S/W will be deployed on reviewer's PCs. 10 Client S/Ws will be able to connect to one Server PC via Network (LAN) at a time.

MiroView™ Server has functionalities: Data Storage, PACS connectivity.

MiroView™ Operator has functionalities: Receiver Management, Case Management and Account Management.

MiroView™ Client has functionalities: List Mode (Case Data Management), Review Mode (Video Display, Image Capture, Annotation Box, etc.), Report Mode (User Comment, Auto Disease Name Check, etc), Export Mode (JPG, AVI, MiroVIew™ file format)

MiroView™ U 4.0 provides some kinds of Modes and Views to help the user review patient video data quickly and conveniently; however, IntroMedic, Co., Ltd. recommends that the doctor review the patient video in the Normal Mode / Single View to prevent from a wrong diagnosis.

MiroView™ U 4.0 is a new version of MiroView™ U 3.0, which has new updated features from the MiroView™ U 3.0. The features are described below:

- Compatibility with New Receiver MR2000: MiroView™ U Operator 4.0
- UI Function for Reviewing Patient Data of Dual Tip Capsule: MiroView™ U Client 4.0
- Support of H.264 Codec: MiroView™ U Common 4.0
- Express Play ver 3.0: MiroView™ U Client 4.0
- Supplementary Play: MiroView™ U Client 4.0

5. Indications for Use

The MiroCam® Capsule Endoscope System is intended for visualization of the small bowel mucosa.

- It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy.

It may be used as a tool in the detection of abnormalities of the small bowel and this device is indicated for adults only.

The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.

6. Technological Characteristics and Substantial Equivalence

The characteristics of the IntroMedic Co., Ltd. MiroCam® Capsule Endoscope System are substantially equivalent to the following current legally marketed predicate devices based on indications for use, typical clinical use, and operational and fundamental technological characteristics

- MiroCam® Capsule Endoscope System by IntroMedic Co., Ltd. K143663
- Given® PillCam® SB3 Capsule endoscopy system by Given Imaging Ltd. K123864
- Given PillCam® COLON 2 capsule endoscopy system by Given Imaging Ltd. K123666 (Reference device)

Table 5-1. Side-by-Side Comparison of the MiroCam® Capsule Endoscope System with the Predicate Device

Type	Characteristics	**MiroCam® Capsule Endoscope System Subject device**	**MiroCam® Capsule Endoscope System K143663**	**Given® PillCam® SB3 Capsule endoscopy system K123864**	**Given PillCam® COLON 2 capsule endoscopy system K123666 (Reference device)**
	Indications for Use	The MiroCam® Capsule Endoscope System is intended for visualization of the small bowel mucosa. - It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy. - It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy. - It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy. It may be used as a tool in the detection of abnormalities of the small bowel and this device is indicated for adults only. The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.	MiroCam® Capsule Endoscope System is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age. The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.	The PillCam SB capsule is intended for visualization of the small bowel mucosa. ● It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy. ● It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy. ● It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy. The suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas. The PillCam SB capsule may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults and children from two years of age.	The PillCam COLON 2 Capsule Endoscopy System is indicated to provide visualization of the colon. It is intended to be used for detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible. (※The Indications for Use of the device do not apply to the subject device.)
	Manufacturer	IntroMedic Co., Ltd.	IntroMedic Co., Ltd.	Given Imaging Ltd.	Given Imaging Ltd.
Caps	Model Name	MC2000-B	MC1200-B	PillCam SB3	PillCam COLON 2

ule	Size	Length: 30.1mm Diameter: 10.8mm	Length: 24.5mm Diameter: 10.8mm	Length: 26.2mm Diameter: 11.4mm	Length: 31.5mm Diameter: 11.6mm
	Weight	3.5g±0.1g	3.25g	3.0±0.1g	2.9±0.03g
	Material	Human Compliance Plastic	Human Compliance Plastic	Biocompatible plastic	Biocompatible plastic
	Dome Material	COP (Cyclo Olefin Polymers)	COP (Cyclo Olefin Polymers)	Polycarbonate	Polycarbonate
	Light	12 White LEDs (each 6 White LEDs)	6 White LEDs	4 White LEDs	8 White LEDs (each 4 White LEDs)
	LED Size	2.0mm(L)*1.25mm(W)*0.8mm(H)	2.0mm(L)*1.25mm(W)*0.8mm(H)		
	LED Viewing Angle	130°	130°		
	Exposure Time	0.5 ~ 24 ms	0.5~24 ms		
	Field of View	170°	170°	156°	
	Image Sensor	CMOS	CMOS	CMOS	CMOS
	Depth of Field	Length: 3cm	Length: 3cm	Length: 3cm	Length: 3cm
	Enlargement Ratio	1:8	1:8		
	Detectable Range	Under 0.1mm	Under 0.1mm	At least 0.07mm	
	Sampling Ratio	6 frames per second (each 3 frames per head)	3 frames per second	2 or 2~6 frames per second	Up to 35 Frames per Second per head
	Pixel size of Sensor	6.0 ㎛*6.0 ㎛	6.0 ㎛*6.0 ㎛		
	Working Time	12 Hours	12 Hours	Over 8 Hours	10 Hours
	Chemical Safety	Safe in pH=2 ~ pH=8	Safe in pH=2 ~ pH=8	Safe in pH=2 ~ pH=8	Safe in pH=2 ~ pH=8
	Battery Type	Silver Oxide Cell	Silver Oxide Cell	Silver Oxide Cell	Silver Oxide Cell
	Optimum working distance	0mm	0mm		
	Direction of View	0°	0°		
	Resolution	320x320	320x320		
	Distortion (%)	-14.5	-14.5		
	Lens Uniformity (%)	79.39	79.39		
	Shelf life	12 months from date manufacture	18 months from date manufacture		12 months from date manufacture
	Operation Temp.	20 ~ 40℃	20 ~ 40℃	20 ~ 40℃	20 ~ 40℃
	Storage Temp.	0 ~ 50℃	0 ~ 50℃	0 ~ 25℃	0 ~ 30℃
	Transmission Methods	HBC (Human Body Communication)	HBC (Human Body Communication)	RF	RF
Rece	Model Name	MR2000	MR1100	DR3	DR3
iver	Recording Time	12 Hours	12 Hours	Up to 15 hours at LCD off	Up to 15 hours at LCD off
	Weight	330g (Include Battery)	350g (Include Battery)	500g (Include Battery Pack)	500g (Include Battery Pack)
	Operation Voltage	3.65Vdc, 0.45A	3.7Vdc, 0.45A	3.5~4.2Vdc, 0.15~0.5A	3.5~4.2Vdc, 0.15~0.5A
	Battery Type	Lithium Ion Battery, 3.65V, 10,500mA	Lithium Ion Battery, 3.7V, 10,400mA	Lithium Ion Battery, 3.8V, 8,800mAh	Lithium Ion Battery, 3.8V, 8,800mAh
	Operation Temp.	0 ~ 40℃	0 ~ 40℃	0 ~ 40℃	0 ~ 40℃
	Storage Temp.	0 ~ 55℃	0 ~ 55℃	0 ~ 55℃	0 ~ 55℃
	Category	Internal power supply, Type BF	Internal power supply, Type BF	Internal power supply, Type BF	Internal power supply, Type BF
	Real Time View	LCD	USB, Wifi	LCD	LCD
	Method of Data Communication	Data Cable or Data Belt (Optional)	Data Cable or Data Belt (Optional)	Sensor Array or Sensor Belt	Sensor Array or Sensor Belt

	Characteristics	IntroMedic Co., Ltd.	IntroMedic Co., Ltd.	Given Imaging Ltd.	Given Imaging Ltd.
Soft ware	Software	MiroView™ U 4.0	MiroView™ U 3.0 MiroView™ RTV (Real Time Viewer Application-only USB) MiroView™ RTV-I (Real Time Viewer Application-only Wifi)	RAPID 8.0	
	Language	English, Spanish, Portuguese, Danish, Chinese, French, Italian, Korean, Dutch, Russian, Swedish	English, Spanish, Portuguese, Danish, Chinese, French, Italian, Korean, Dutch, Russian, Swedish	English, French, German, Italian, Spanish, Portuguese, Dutch, Swedish, Finish, Danish, Chinese-Mandarin, Korean, Russian, Greek	
	Data Export	JPEG Image, AVI Video Clip, PDF Report Data, ODF (Open Data Format), EXMIF (Exchangeable Medical Information Format)	JPEG Image, AVI Video Clip, PDF Report Data, ODF (Open Data Format), EXMIF (Exchangeable Medical Information Format)	JPEG Images, (MPEG) Video clips, grml (Given proprietary) files, PDF Reports, generic XML-format, Capsule Endoscopy report data	
	Data Display	Single and Multi Image, Time Bar, Diagnosis Data, Dual Bar	Single and Multi Image, Time Bar, Diagnosis Data	Single and Multi Image, Time Bar, Colorbar with region specific color and other diagnostic data	
	Event Marker	Small Image with Explanation	Small Image with Explanation	Annotated thumbnails	
	Display Ratio	3~10,000fps	3~10,000fps	5~80fps	
	Display Mode	Single View, Dual View, Quad View, Range View, Map View	Single View, Dual View, Quad View, Range View, Map View	Single View, Dual View, Quad View, Mosaic View, Dual Head View	
	Running Mode	Normal Mode, Express, SGIB	Normal Mode, Express, SGIB	Normal, Auto, Quick View, SBI	

For the predicate device and the subject device, this has all the same performances except Receiver and Software.

[Capsule]

Subject device uses the same optical system as Capsule of Predicate device K143663. It means that this optical system uses the same parts as those of K143663 such as Sensor, LED, and Lens. However, the K143663 Capsule can only shoot in one direction, but the subject device can shoot in both directions. Two-way Capsule has the advantage of eliminating blind spots by two-way shooting because it has two identical optical systems compared to one-way Capsule. This is comparable to that of the Predicate device in terms of effectiveness. And this two-way Capsule endoscope system has the reference device, COLON 2, K123666. The COLON 2 is able to expand indications for use from diagnosis of colon to diagnosis of small bowel due to the advantages of bi-directional photography and increased frame number. The frame number of this submitted the subject device is smaller than that of the reference device and because it cannot prove the effectiveness of colon diagnosis, the reference device is limited to small bowel diagnosis. In addition, the subject device is smaller in size than the COLON 2 of the

reference device K123666, which makes ease of ingestion easier.
And because two optical systems are used compared to K143663, Operating Time and Shelf Life can be different, and it is proved that there is no problem in operating time when using within the given period through Performance and Bench Test.

- Ease of device ingestion

  The size of MC2000-B is 30.1mm x Ø10.8mm. This is smaller than the 31.5mm x Ø11.6mm of the previously FDA clearance device COLON 2 (K123666). So ease of device ingestion of subject device is smaller than COLON 2 (K123666) and can be claimed to be easier to ingest.

The predicate device K143663 and the subject device are using the same sensor (ASPIN), LED and battery. However, the subject device has two image sensors in each head of the capsule and two sensors capture images alternately, so that the total current can be minimized. (See "Hand Shaking Mode for Dual camera")

Hand Shaking Mode for Dual camera

ASPIN supports dual camera mode. One of the two chips is set to operate in Master mode by setting the SEL_SAVE pin to "LOW" while another chip must be set to operate in Slave mode by setting the SEL_SLAVE pin to "High". In Dual mode, the hand shaking operation is implemented using HAND1 pins. In Master mode, HAND0 operates as output and HAND1 operates as input. In slave mode the situation is opposite. Timing diagram is shown below.

1) Master device EEPROM data read: time interval ①
2) Slave device EEPROM data read: time interval ②
3) Master dummy tx period: time interval ③
4) Slave dummy tx period: time interval ④
5) Master tx. Slave idle: time interval ⑤, ⑦
6) Slave tx. Master idle: time interval ⑥, ⑧

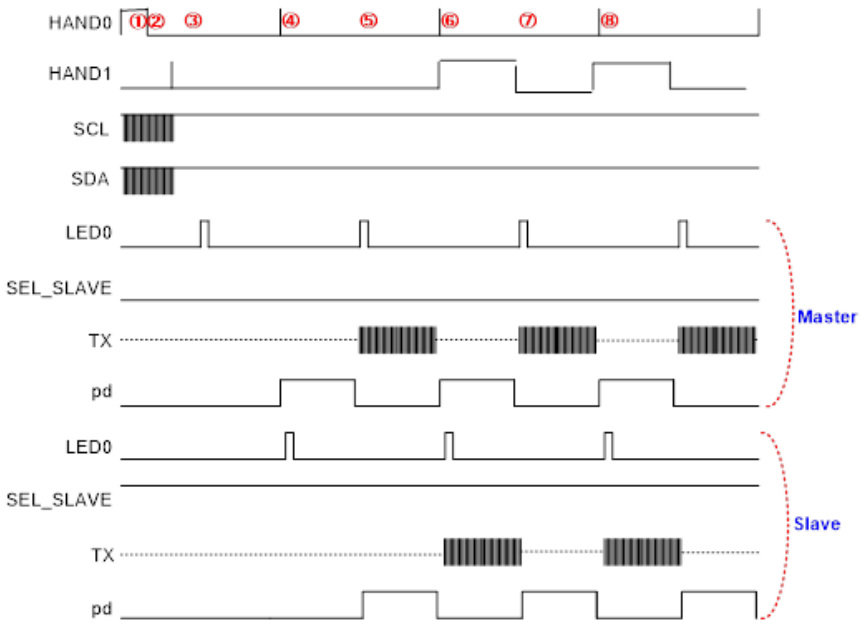
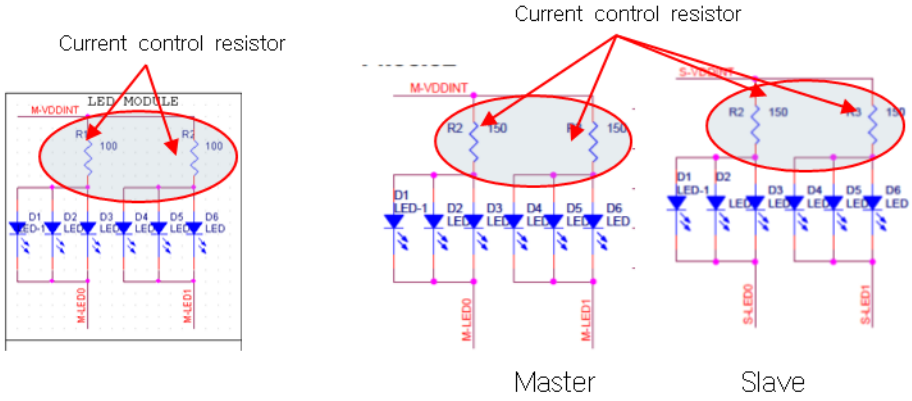


Figure 12-1_Hand Shaking Mode operation

Changing of battery voltage caused by LED connected with control current resistance than entire battery voltage changes due to increase of LED resistance has no affect on image quality.



LED Module of MC1200-B LED Module of MC2000-B

Figure 12-2_Comparison LED Module

For the MC1200-B, Auto Exposure time is used to adjust the LED turn-on time depending on the target brightness, which applies equally to the MC2000-B.

AE (Auto Expose Control) Depending on the sensor's incident light intensity, the AE function optimally adjusts the exposure time, thus preventing the over-exposure and low exposure situations. Namely, it calculates an average brightness of the image and, after checking the present state of the exposure, adjusts the exposure doze to make sure that the current average brightness converges to target brightness value by means of P-control. ASPIN adjusts the exposure time by adjusting the pixel control timing as well as LED ON-time. The unit step of exposure time adjustment is 1 PCLOCK period.

[Receiver]

The Human Body Communication (HBC) method is used on both Subject device and Predicate device (K143663). Even if, Subject device and Predicate device share same communication method, they have different way to display real time view (RTV). Predicate device displays RTV using another device such as laptop and tablet PC via USB or wifi connection, abd Subject device displays these RTV on LCD on the receiver, similar way to Predicate device (K123864).

Another difference, electro-mechanically can be found between K143663 and Subject device but we conducted Safety and EMC test to verifie both devices are safe.

[Software]

MiroView™ U 4.0 is a new version of MiroView U 3.0, which has new updated features from the MiroView™ U 3.0. The features are described below:

- Compatibility with New Receiver MR2000: MiroView™ U 4.0 Operator
- UI Function for Receiving Patient Data of Dual Tip Capsule MC2000 Series: MiroView™ U Client 4.0
- Support of H.264 Codec: MiroView™ U 4.0
- Express Play 3.0: MiroView™ U Client 4.0
- Supplementary Play: MiroView™ U Client 4.0

7. Performance Testing

The MiroCam® Capsule Endoscope System performance testing was done for the submission of predicate device but it was not included when Sensor Bench testing, MTF Measurement testing (including the predicate device, K143663), Minimum Distinguishable Contrast Value and Depth of Field testing (including the predicate device, K143663), Geometric distortion testing (including the predicate device, K143663), Field of View testing (including the predicate device, K143663), Color Reproduction testing (including the predicate device, K143663), Testing optical spectra of the light source at different

time points during the battery life period (including the predicate device, K143663), Testing intensity change during the shelf life period (including the predicate device, K143663), Bite testing, Water proof testing, pH resistance testing, MR1100 (predicate device, K143663) and MR2000 (subject device) Equivalent Performance Comparison testing, and Shelf life testing (Operation time, Package integrity, pH resistance and Bite) was done. The results of this performance testing conclude that the material and technological characteristics have not diminished the safety and effectiveness of the IntroMedic Co., Ltd. MiroCam® Capsule Endoscope System device when compared to the predicate device.

8. Conclusion

Based on Indications for Use, Substantial Equivalence, Performance testing of the devices, IntroMedic Co., Ltd. believes that the MiroCam® Capsule Endoscope System and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.