February 7, 2018

Nemoto Kyorindo Co., Ltd.
Jim Knipfer
General Manager, Overseas Department
Profit Building 5F
2-27-3 Hongo, Bunkyo-ku
Tokyo, Japan 113-0033

Re: K173450
Trade/Device Name: PRESS DUO elite, PRESS DUO elite AG
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: October 31, 2017
Received: November 6, 2017

Dear Jim Knipfer:

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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173450

Device Name
PRESS DUO elite, PRESS DUO elite AG

Indications for Use *(Describe)*
The PRESS DUO elite is intended to be used for injecting contrast media and common flushing solution into the vascular system in Angiographic and Computed Tomography (CT) procedures whereas the PRESS DUO elite AG is intended to be used for injecting contrast media and common flushing solution into the vascular system for Angiographic procedures 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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K173450
PRESS DUO elite and PRESS DUO elite AG
Contrast Delivery System 510(k) Summary

Contact Name: Jim Knipfer
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Date Prepared:	November 2, 2017
Proprietary Name(s):	PRESS DUO elite, PRESS DUO elite AG
Common Name:	CT/Angiography Contrast Media Delivery System
Classification Name:	Injector and Syringe, Angiographic
Predicate Device(s):	Angiomat Illumena Injector, K963071 (Primary predicate)
	Dual Shot alpha 7, K133189 (Secondary predicate)
	Rempress, K092896 (Secondary predicate)
	Medrad Mark 7 Arterion Injection System, K132928 (Secondary predicate)

Indications for Use / Intended Use:

The PRESS DUO elite is intended to be used for injecting contrast media and common flushing solution into the vascular system in Angiographic and Computed Tomography (CT) procedures whereas the PRESS DUO elite AG is intended to be used for injecting contrast media and common flushing solution into the vascular system for Angiographic procedures only.

Description:

The main components of the PRESS DUO elite and PRESS DUO elite AG are the Console, Powerhead and Main Control Unit. The basic configurations of the PRESS DUO elite and PRESS DUO elite AG are a pedestal, ceiling mount or table mount configuration. With any configuration, the three main components are most often contained in the angiographic suite and normally near the patient. The parameters of the injection, such as volume, flow rate and pressure are programmed by the operator via the graphical user interface

with touchscreen input. The system is designed to deliver a variety of injection protocols. It can deliver single or multiple phase injections. The Console is powered via 24 volts DC which is derived from a remote AC to DC converter (like that used with laptop computers) and communicates with Main Control Unit communications interface cable. After the injection protocol has been set, the Powerhead performs the injection by driving the lead screw ram. The ram pushes the push-rod of the syringe which expels fluid from the barrel of the syringe. The only difference between the PRESS DUO elite and PRESS DUO elite AG is the availability of the CT Mode. The PRESS DUO elite provides both an Angiographic Mode and CT Mode of operation whereas the PRESS DUO elite AG has the CT Mode of operation turned off in the software and cannot be turned on by the user. All other software, hardware and mechanical aspects of the PRESS DUO elite and PRESS DUO elite AG are identical. The following paragraphs provide more details for each of these main components.

POWERHEAD: The Powerhead provides a means for accepting and identifying a given syringe and then applying a force to the plunger of the syringe via its screw driven ram which will eject the contrast or common flushing solution from the barrel of the syringe. The Powerhead is in constant communications with the Main Control Unit for determining injection protocol and to monitor all Powerhead functions and injection sequences. The injection information is communicated to the user Console to provide immediate feedback of injection operation. As highlighted in the Description section of this document there are 3 configurations for the PRESS DUO elite and PRESS DUO elite AG. These configurations refer to where the Powerhead component would be located 1) pedestal stand, 2) ceiling suspension system or 3) table rail mounted.

CONSOLE: The Console is the main user interface for the PRESS DUO elite and PRESS DUO elite AG. It provides a color graphical user interface with an overlying touchscreen for easy injection monitoring and injection setup. At the completion of an injection the injection results are clearly displayed to the user. The Console provides a connection for a remote Handswitch that can be used to start or stop an injection. The Console resides normally in the angiographic suite and is typically located near the patient.

MAIN CONTROL UNIT: The Main Control Unit is the interface between the Console and the Powerhead. The Main Control Unit receives the user input data from the Console and converts to the necessary control information then relays to the Powerhead. The Main Control unit also provides the power necessary to operate the Powerhead. The Main Control Unit is located inside the angiographic suite and communicates with the Console via a communications link.

SYRINGES AND ACCESSORIES: The PRESS DUO elite and PRESS DUO elite AG injection system have only

one compatible syringe which is a 150ml single use disposable syringe as defined by 510(k) K090487, manufactured by Coeur, Inc. Other consumable accessories such as tubing, valves, stop cocks, are required to have luer connections compliant to ISO594-2 and shall have a pressure rating consistent with the pressure limit set-point on the PRESS DUO elite or PRESS DUO elite AG or a maximum of 1200PSI.

SUBSTANTIAL EQUIVALENCE

A comparison chart shown in Table 1 compares the technological characteristics of the PRESS DUO elite and PRES DUO elite AG contrast delivery systems to the predicate devices the Liebel-Flarseim's Angiomat Illumena, Nemoto's Dual Shot alpha 7, Nemoto's Rempress and Medrad Mark 7 Arterion. The PRESS DUO elite and PRESS DUO elite AG is substantially equivalent to the predicate devices.

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Characteristic / Feature	Angiomat Illumena (Primary Predicate) K963071	Dual Shot alpha 7 (Secondary Predicate) K133189	REMPRESS (Secondary Predicate) K092896	Medrad Mark 7 Arterion (Secondary Predicate) K132928	PRESS DUO elite PRESS DUO elite AG (K173450)	Device Comparison Result
Multi-phasic Injections	4 phases per protocol	5 phases per protocol	1 phase per protocol	4 phases per protocol	2 phase per protocol	Same
Single or Dual Syringe	Single	Dual	Single	Single	Dual	Same
Angio and CT Modes	Angio, CT	CT	Angio	Angio	Angio, CT	Same
Infusion Mode	Yes	No	Yes	No	Yes	Same
Protocol Storage	45 protocols (Angio Mode) 45 protocol (CT Mode)	400 protocols	20 protocols	40 protocols	240 protocols	Inside Specification
X-ray/Scan Delay	0 – 300 secs.	0 – 300 secs	0 – 99 secs	0 – 99.9 secs	0 – 99.9 secs	Inside Specification
Inject Delay	0 – 300 secs.	No	0 – 99 secs	0 – 99.9 secs	0 – 99.9 secs	Inside Specification
Inter-phase Delay	0 – 300 secs.	0 – 300 secs	None	Not indicated	None	Same
Syringe System	150ml or 125ml	100ml or 200ml	150ml	150ml	150ml	Same
Volume Remaining Display	LED display on Powerhead	Optional Powerhead display	LED display on Powerhead	Color LCD	LED display on Powerhead	Same
Filling Rate	3 to 25ml/sec (manual)	0.5ml/sec, 1.5ml/sec and 8.0ml/sec	0.5 – 2.5ml/sec	1 – 10ml/sec	0.5 – 2.5ml/sec	Same
Rise Time	0 to 10 seconds	Off = 0 secs, On = 2 secs	0 – 9.9 seconds	0 – 9.9 secs	0 – 9.9 seconds	Same
Arming Modes	Single or Multi	Single	Single or Multi	Single or Multi	Single or Multi	Same
Variable Jog Speeds	Yes	Yes	Yes	Yes	Yes	Same
Body Weight Protocol	No	Yes	No	No	No	Same
Quick Return	No	Yes (see Filling Rate)		Not Indicated	Yes (see Filling Rate)	Same
Quick Purge	No	Yes	No	Not Indicated	Yes	Same
Remote Start	Yes	Yes	Yes	Yes	Yes	Same
Pressure Graph	Not indicated	Yes	Yes	No	Yes	Same
Syringe Heater	Yes	Yes	Yes	Yes	Yes	Same
Interlocking with Angio	Yes	No	Yes	Yes	Yes	Same
Interlocking with CT	Not indicated	Yes	No	No	No	Same
Injection Abort	Yes	Yes	Yes	Yes	Yes	Same
Powerhead Indicator Lights	Yes	Yes	Yes	Yes	Yes	Same
Power-On Self-Test	Yes	Yes	Yes	Yes	Yes	Same
Selectable Inject Patterns	Yes	Yes	Yes	Yes	Yes	Same
Variable Flow Rate	No	No	Yes – optional	Yes - optional	No	Same
Flow Rate	0.1 to 40ml/sec for 125/150ml syringe (Angio Mode) 0.1 to 10.0ml/sec in (CT Mode) 0.1 to 99ml/min for infusion purposes	0.1 to 10ml/sec in 0.1ml/sec increments	0.1 to 25ml/sec with 150ml syringe 0.1 to 99ml/min for infusion purposes	0.1 to 45ml/sec in 0.1ml/sec increments 0.1 to 59.9ml/min in 0.1ml/min (not specified as infusion mode but operates at infusion rates)	0.1 to 30ml/sec in 0.1ml/sec increments (Angio Mode) 0.2 to 10.0ml/sec in 0.1ml/sec increments (CT mode)	Inside Specification
Pressure Limit	75 - 1200 PSI (Angio Mode) 75 - 300 (CT Mode)	25 to 300 PSI	50 – 1200 PSI	100 – 1200 psi	50–1200 PSI (Angio Mode) 50–300 PSI (CT Mode)	Same
Remote Start Switch	Yes	Yes	Yes	Yes	Yes	Same
Test Shot	Yes (Re-Arming)	No	Yes (Trace Shot)	Yes (Re-arming)	Yes (Re-Arming)	Same
Safety Stop Mechanism	Electrical stop when injection parameters are out of specification	Electrical stop when injection parameters are out of specification	Electrical stop and mechanical backup stopper when injection parameters are out of specification	Electrical stop when injection parameters are out of specification	Electrical stop when injection parameters are out of specification	Same
User Interface Features						
- Fill / Expel Control	Yes	Yes	Yes	Yes	Yes	Same
- Air Detection	Operator visual inspection	Operator visual inspection	Operator visual inspection	Operator visual inspection	Operator visual inspection	Same
- Programming Injection	Touchscreen	Touchscreen	Touchscreen	Touchscreen	Touchscreen	Same

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- Status Display	Powerhead lights	Powerhead lights	Powerhead lights	Powerhead lights	Powerhead lights	Same
- Console Display	Color LCD with touchscreen	Color LCD with touchscreen	Color LCD with touchscreen	Color LCD with touchscreen	Color LCD with touchscreen	Same
Materials	Plastics and metals	Plastic and metals	Plastics and metals	Plastic and metals	Plastic and metals	Same
Anatomical Sites	Arterial and Venous injections	Arterial and venous injections	Arterial and Venous injections	Arterial and Venous injections	Arterial and Venous injections	Same
Intended Use Statement	The Angiomat Illumena is designed to inject radiopaque contrast medium into the vascular system for Angiography and CT procedures as prescribed by qualified health care professionals.	The contrast delivery system Dual Shot alpha 7 is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-ray tomography (CT).	The contrast delivery system REMPRESS is an intravascular injection system intended for the administration of contrast media or flushing solutions used in conjunction with angiographic imaging procedures.	The MEDRAD Mark 7 Arterion Injection system is intended to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies.	The PRESS DUO elite is intended to be used for injecting contrast media and common flushing solution into the vascular system in Angiographic and Computed Tomography (CT) procedures whereas the PRESS DUO elite AG is intended to be used for injecting contrast media and common flushing solution into the vascular system for Angiographic procedures only.	Same
Target Population	Humans	Humans	Humans	Humans	Humans	Same

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SUMMARY OF PERFORMANCE TESTING

Performance testing was completed to verify the PRESS DUO elite and PRESS DUO elite AG contrast delivery systems are capable of achieving the specification parameters for the system as outlined in the substantial equivalence chart. Verification of the system's ability to accurately achieve these values validates the substantial equivalence claims. Injection performance was tested to verify accuracy of delivered flow rate, volume, pressure and manual control speeds.

The EMC, Electrical, Mechanical and Thermal Safety testing was performed using a prototype device however there were no electrical, safety or structural mechanical differences between the tested device and final device. A ferrite bead shown in the test reports for the prototype device is also included in the final device. One variation between the tested device and the final device is a Footswitch. The Footswitch was included in the testing as this optional component is provided to our customers outside of the USA however it would not be provided to USA customers since the option is not required.

Testing was not specifically performed with the PRESS DUO elite AG model however the functionality of the PRESS DUO elite AG can be tested using the PRESS DUO elite model since it can perform both angiographic functions and the CT functions which are not included in the PRESS DUO elite AG. The utilization of the PRESS DUO elite further permits this disabling of the CT Mode thereby making it a PRESS DUO elite AG model. All performance specifications when operating in the Angio Mode are identical between the PRESS DUO elite and PRESS DUO elite AG, therefore separate testing was not necessary to confirm the PRESS DUO elite AG operation.

The sample size used for the testing was a single unit of the PRESS DUO elite. The justification for testing only a single unit is based upon our long history of the PRESS DUO in the Japanese market. The PRESS DUO has been on the Japanese market for approximately 5 years therefore the performance of the device is well understood and substantiated by the existing market.

With respect to consumables used during the testing, the only compatible syringe is the 150ml disposable syringe identified in K090487, which is reflected in the User Manual. Therefore, the 150ml syringe was used for all testing. The 150ml connection point is compliant to ISO594-2 therefore compatible with any tubing compliant to ISO594-2 and 1200PSI requirement. The ISO594-2 and 1200PSI requirements are also reflected in the updated User Manual. The extension tubing H-70 used in this testing is compatible with the required specifications. All needles and catheters on the market today that comply with the ISO594-2 specification can be used with the 150ml syringe in K090487 which is compatible with the Protection Cover

that is used with the PRESS DUO elite and PRESS DUO elite AG.

To develop injection pressure various needles are used during the performance testing to ensure the injector can be forced to perform a pressure limited injection. A pressure limited injection is required to verify the necessary hardware and software mechanisms are in place and functioning correctly to prevent an over pressure limit situation from presenting itself. Various needles are used to enable the pressure limit condition to occur at different Flow Rates. The 21G and 23G needle sizes are sufficient to force the injector device into pressure limit conditions at various flow rate values. Since the pressure is limited by the injector a smaller orifice size would not cause the pressure to limit to change. For example, the execution of an injection using a 23G needle which is pressure limiting at 500PSI would still pressure limit at 500PSI using a 24G (smaller) needle. The pressure limit is set by the injector device and not by the needle, tubing etc.

VOLUME

Fluid delivery of an injector is characterized by three primary parameters, flow rate, volume and pressure limit. The volume delivered is the most critical parameter in that is has the greatest effect on image quality. During testing, the volume delivered was accurately measured and compared to the volume programmed. Over the range of volumes programmed, the PRESS DUO elite and PRESS DUO elite AG contrast delivery system successfully delivered the volumes within the allowable specifications.

FLOW RATE

The second most critical variable parameter in delivering fluid to a patient is the flow rate. During the test injections, the injection time and volume were recorded then the flow rate calculated. In the event of a pressure limit injection, the volume and time are known not to accurately represent the flow rate therefore the data was omitted from this specific calculation. In all non-pressure limited injections the flow rate measured within the allowable ranges of the specification. NOTE: Pressure limit injections automatically reduce the flow rate from the user set flow rate to maintain a constant pressure, as desired by the operator.

PRESSURE

During all injections, the PRESS DUO elite and PRESS DUO elite AG monitors the pressure to determine if the injection should be pressure limited. An upper limit is set for the syringe used in the injector in order to avoid failure of the syringe. During testing, the actual pressure was measured and compared to the displayed values and product specifications. All pressure readings were within the allowable specifications.

MANUAL CONTROL SPEEDS

The PRESS DUO elite and PRESS DUO elite AG have two speeds for manually moving the rams. By

depressing the forward or reverse keys on the Powerhead, the rams can be moved at varying speeds. By pressing the forward or reverse key in combination with the accelerator key, the rams can be moved at maximum speed. During testing, speeds were confirmed to be within the allowable specification range.

USABILITY AND HUMAN FACTORS

The PRESS DUO elite and PRESS DUO elite AG were reviewed for usability and human factors and as a result of our use-related risk analysis, reference Section 16 document CB00-13-001F Section 8.8 use-analysis items 1 though 48 of the submission documents, the PRESS DUO elite and PRESS DUO elite AG do not contain critical task and all use-related risk are mitigated to be ALARP through design and product labeling as indicated in the CB00-13-001F document.

CONCLUSION

The PRESS DUO elite and PRESS DUO elite AG contrast delivery systems demonstrated their ability to perform within its specified parameters and operate as intended by the users of the devices. As a result, its performance is deemed acceptable and substantially equivalent to the predicate devices.