1 General Information

1.1 Manufacturer

Company Name	INVIA, LLC 3025 Boardwalk Dr, Suite 200 Ann Arbor, MI 48108 U.S.A.
DUNS #	62-136-0762
PRRC	Edward Ficaro, President

1.2 Product Family Name: Corridor4DM

Software application to analyze and review radiographic images.

INVIA's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion images.

The application supports correlative review and measures of physiologic, functional, and anatomic datasets from multidimensional radiographic images. Corridor4DM provides analytical tools to help the user quantify and document changes in these measures.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate multimodality datasets. The Corridor4DM application is a complement to these standard procedures.

GMDN Code: 57812
GMDN Term: Radiology DICOM image processing application software

1.3 Family Releases:

Basic UDI-PI: 08649740002C4DM10SR

Model	Description	Market Introduction Date
v2024	Nuclear Cardiac Quantification Software	Q4 2023
v2023	Nuclear Cardiac Quantification Software	March 30, 2023
v2018	Nuclear Cardiac Quantification Software	Dec 5, 2019
v2017	Nuclear Cardiac Quantification Software	May 4, 2017
v2016	Nuclear Cardiac Quantification Software	July 15, 2016
v2015	Nuclear Cardiac Quantification Software	March 20, 2015
v2013	Nuclear Cardiac Quantification Software	August 26, 2013
v2012	Nuclear Cardiac Quantification Software	October 29, 2012
v2010	Nuclear Cardiac Quantification Software	November 4, 2010

2 Registrations and Certifications

2.1 ISO 13485 / EN ISO 13485 Certification

Cert #	Certificate Scope	Initial Issue Date	Current Issue Date	Exp Date
US10/81410	Design, development, manufacturing, contract manufacturer, distribution and installation of medical imaging software/systems for the analysis of nuclear, PET and CT images.	28 Sept 2010	21 Feb 2022	26 Feb 2025

2.2 Directive 93/42/EEC Certification (Annex II, excl. Section 4) – (with SGS-Belgium, NB 1639)

Cert #	Certificate Scope	Initial Issue Date	Current Issue Date	Exp Date
US19/819943496	Software/systems for the analysis of radiographic (nuclear, PET and CT) medical images. Corridor4DM – Nuclear Cardiac Quantification Software	28 Sept 2010	16 Dec 2019	26 Feb 2024

2.3 MDSAP (ISO 13485:2016) Certification

MDSAP Cert #	Certificate Scope	Initial Issue Date	Current Issue Date	Exp Date
US19/819943340	Design, development, manufacturing, contract manufacturer, distribution, and installation of medical imaging software/systems for the analysis of nuclear, PET and CT images.	27 Aug 2019	24 Feb 2022	23 Feb 2025

2.4 United States FDA

Establishment Registration #	Establishment Type	Device Listing		
		Regulation #	Pro Code	Device Class
3004993756	Manufacturer, Contract Manufacturer	892.1200	KPS	2
		892.1750	JAK	2
		892.2050	LLZ	2

3 Regulatory Compliance Entities

Auditing Organization (ISO 13485, MDSAP)	Notified Body (93/42 EEC MDD)
Notified Body #: 0120 **SGS United Kingdom Ltd** Rossmore Business Park, Ellesmere Port Cheshire, CH65 3EN, United Kingdom Phone: +44 (0) 151 3506666 www.sgs.com	Notified Body #: 1639 **SGS Belgium NV** SGS House, Noorderlaan 87 Antwerp, 2030 Belgium Phone : +32(0)3 545 48 48 Fax : +32(0)3 545 48 49 www.sgs.com

4 Regulatory Registrations

4.1 Australia

Intended Use	INVIA's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion images. The application supports correlative review and measures of physiologic, functional, and anatomic datasets from multidimensional radiographic images. Corridor4DM provides analytical tools to help the user quantify and document changes in these measures. Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate multimodality datasets. The Corridor4DM application is a complement to these standard procedures.
Territory Representative	Emergo Australia Darling Park, Tower II, Level 20 201 Sussex Street Sydney, NSW 2000 Australia
Market Authorization / Required Certifications	US19/819943340 (MDSAP Certification)
Certificate Scope	See MDSAP Certificate in Section 2
Device Classification	Class IIa
Device License ID (ARTG)	308375 assigned 20/08/2018 for Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Radiology DICOM image processing application software
Initial Date Rec'd	June 12, 2010
Expiration Date	Annual renewal (AS)

4.2 Canada

Manufacturer ID	132619
Intended Use (This was provided on device license application submitted on 2010-11-11)	The Corridor4DM is a software application design to process review, and quantitatively analyze data files of patient studies acquired on nuclear medicine (NM), PET, and CT medical imaging cameras. The application provides tools to process, quantify, and display the data file, in order to assist cardiac physicians in their patient assessments. Corridor4DM is intended to be used only by trained medical professionals. Primary medical conditions for which this software is utilized are related to cardiovascular disease where diagnostic imaging is clinically indicated (e.g. evaluation of coronary artery disease). The Clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual assessment.
Territory Representative	NA
Market Authorization / Required Certifications	US19/819943340 (MDSAP Certification)
Device Classification	Class 2
Device License Number	84709
Initial Date Rec'd	Dec 09, 2010
Expiration Date	Annual renewal (INVIA)

4.3 European Union

Manufacturer SRN	US-MF-000008976	
Intended Use	INVIA's ***Corridor4DM*** application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion images. The application supports correlative review and measures of physiologic, functional, and anatomic datasets from multidimensional radiographic images. 4DM provides analytical tools to help the user quantify and document changes in these measures. Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate multimodality datasets. The 4DM application is a complement to these standard procedure	
Territory Representative	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands	**SRN:** NL-AR-000000116
Market Authorization / Required Certifications	US19/819943496 - EC 93/42/EEC Certification	
Certificate Scope	Software/systems for the analysis of radiographic (nuclear, PET and CT) medical images. Corridor4DM – Nuclear Cardiac Quantification Software	
Device Classification	Class IIa	
Device License ID	08649740002C4DM10SR (Basic UDI-DI)	
Initial Date Rec'd	Sept 28, 2010	
Expiration Date	Feb 26, 2024 (MDD Certificate expiry)	

4.4 India

Intended Use	Same as IFU	
Territory Representative / Importer	Morulaa Health Tech Pvt Ltd, Plot No 38, First Floor, Rajeswari Street, Santhosh Nagar, Kandanchavadi, Chennai, Tamil Nadu (India) - 600096 Tel: 044-42183366 FAX: 044-42161313	File No: HQ/MD/2022/001494
Market Authorization / Required Certifications	None (MD-15, Medical Device Rules 2017)	
Device Classification	Class B	
Device License ID	License No: IMP/MD/2023/000014	
Initial Date Rec'd	9-Jan-2023 (Import License)	
Expiration Date	June 2027 (AR)	

4.5 Israel

Intended Use	INVIA's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion images. The application supports correlative review and measures of physiologic, functional, and anatomic datasets from multidimensional radiographic images. 4DM provides analytical tools to help the user quantify and document changes in these measures. Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate multimodality datasets. The 4DM application is a complement to these standard procedure
Registration Holder	I.L EMERGO Israel Ltd. Andrei Sakharov 9 Building 25, 8th floor Matam North Haifa, 3190501 Israel
Device Classification	IIa (follows DoC, CE Mark)
Initial Date Rec'd	June 30, 2016 (best estimate)
Expiration Date	Dec 31, 2024 (Israel registration extension notice released November 1, 2023)

4.6 Saudi Arabia

Intended Use	Corridor4DM Personal Software application to analyze nuclear medicine PET and CT patient studies.	
Authorized Representative	Bio Standards Building No: 5058 Mohammad Ben Abed Al Aziz Street Sulimaniyah Unit No : 5 AR Riyadh, 12243-7061 Kingdom of Saudi Arabia Riyadh	We maintain AR license (ARL-2019-MD-1935) with Bio Standards from the SFDA. We renewed for 10 year: Exp 2-Feb-2030
Market Authorization / Required Certifications	None	
Device Classification	Class II Medical Software	

Device Registration:	ME0000002153SFDAA (Medical Device National Listing Number)
Initial Date Rec'd	Apr 15, 2014
Expiration Date	MDMA Registration: 05-Apr-2025 (3 year renewal)

4.7 Singapore

Device Name	INVIA Corridor4DM Personal
Intended Use (US FDA)	INVIA's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion emission tomographic images. Cardiac CT interpretation and calcium quantification are optional features that are integrated into Corridor4DM (SPECT-CT and PET-CT). The calcium scoring package is a non-invasive diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, a risk factor for coronary artery disease. Co-registration or fusion of volumetric data (ECT and/or CT) is provided as a quality control for the identification of structures where correlative spatial information is necessary for a diagnostic interpretation.
Territory Representative	Emergo Singapore Consulting Private Limited 1 Fullerton Road One Fullerton, #02-01 Singapore 049213
Importer	Agfa Healthcare Singapore Pte Ltd 33 UMI Avenue 3 Vertex, #07-15 Singapore 408868
Market Authorization / Required Certifications	None
Device Classification	Class B
Device Registration	DE0500391
Initial Date Rec'd	Feb 18, 2016
Expiration Date	Feb 17, 2024 (AR)

4.8 Switzerland

Intended Use	Same as IFU	
Territory Representative	MedEnvoy Switzerland Gotthardstrasse 28 Zug 6302 Switzerland	CHRN: CHRN-AR-20000310
Market Authorization / Required Certifications	US19/819943496 - EC 93/42/EEC Certification	
Device Classification	Class IIa	
Device Registration	Registration not yet available for non-Swiss manufacturers.	
Initial Date Rec'd	March 8, 2022	
Expiration Date	Not specified	

4.9 UK

Intended Use	Same as IFU

Territory Representative	Emergo Consulting (UK) Limited c/o Cr360 – UL International Compass House Vision Park Histon Cambridge CB24 9BZ, United Kingdom
Market Authorization / Required Certifications	US19/819943496 - EC 93/42/EEC Certification
Device Classification	Class IIa
Device Registration	08649740002C4DM10SR (Basic UDI-DI)
Initial Date Rec'd	Dec 21, 2021
Expiration Date	Dec 21, 2024 (AR)

4.10 US/FDA

Intended Use	INVIA's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion emission tomographic images. Cardiac CT interpretation and calcium quantification are optional features that are integrated into Corridor4DM (SPECT-CT and PET-CT). The calcium scoring package is a non-invasive diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, a risk factor for coronary artery disease. Co-registration or fusion of volumetric data (ECT and/or CT) is provided as a quality control for the identification of structures where correlative spatial information is necessary for a diagnostic interpretation.	
Territory Representative	INVIA, LLC 3025 Boardwalk Dr, Suite 200, Ann Arbor, Michigan 48108	Establishment Registration No: 3004993756
Market Authorization	510(k) K101279	
Device Classification	Class II	
Device Listing Number	D206243	
Initial Date Rec'd	Aug 9, 2010	
Expiration Date	Annual Renewal (INVIA)	