NEXTGEN MD INITIATIVE

13 June 2024

Medical Devices Cluster

Health Sciences Authority

Background

- Medical devices often undergo numerous iterations to enhance the product based on real-world experience and feedback
- Although there are successive improvements and refinements, next generation devices may share common characteristics and validation data with their predecessors
- They are typically rebranded to distinguish them from their predecessors and to highlight the enhancements incorporated
- Next generation devices generally cannot be registered via the Change Notification (CN) pathway, as the spirit of change management is intended for modifications to the registered device or the expansion of registered variations

Objective

To facilitate the registration of next generation devices by streamlining the registration process to allow applicants to leverage data that has been submitted to HSA for registered devices

Eligibility Criteria

The next generation device must meet the following:

- **Class B, C and D** (except MD-drug combination) device submitted under FULL route

General Medical Devices	In-Vitro Diagnostic Medical Devices
All models in the application must meet ALL of the following criteria when compared with the registered device: a) Same product type b) Identical validation for Biocompatibility, Sterilization AND Shelf-life	All reagents in the application must share ALL of the following criteria when compared with the registered device: a) Identical formulation AND labelled storage condition b) Identical intended use and indications for use c) Identical sample type

Note: Only identical test reports (same report version) previously submitted to HSA can be leveraged

The registered device must meet the following:

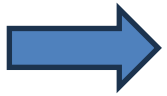
- Same **Product owner** and **Registrant** as the next generation device
- Registered with HSA via ABRIDGED or FULL route.
  - If you are leveraging the changes made to the registered device, the changes must be registered via a REVIEW or TECHNICAL CN
- Registered on SMDR (i.e., active listing) at point of submission of the next generation device

How to enrol?

Submit product registration via MEDICS

Documentary submission as per GN-15

NextGen MD Form



Drop us an email of the job reference number at hsa_md_info@hsa.gov.sg with subject title 'NextGen MD Initiative'

NOTE:

- Once the form is submitted, no further amendments should be made
- If information required in NextGen MD Form is incomplete (i.e., eligibility criteria and supporting documents are not met/submitted), the application will be reviewed per the standard FULL evaluation route. No further clarifications will be sent

This is an opt-in initiative (not mandatory).

Effective date: 1 July 2024

NEXTGEN MD FORM

Please note that the premarket registration submission requirements per GN-15 still applies. You can include the information from Part 1 and 2 of this form as an appendix to this form. ***If the information provided within this form is incomplete, the application will be reviewed as per the standard FULL evaluation route.***

Qualifying criteria

General Medical Devices	In-Vitro Diagnostic Medical Devices
All models in the application must meet ALL of the following criteria when compared with the registered device: a) Same product type b) Identical validation for Biocompatibility, Sterilization AND Shelf-life	All reagents in the application must share ALL of the following criteria when compared with the registered device: a) Identical formulation AND labelled storage condition b) Identical intended use and indications for use c) Identical sample type

PART 1 COMPARISON TABLE OF NEXT GENERATION DEVICE AND REGISTERED DEVICE

	Next generation device	Registered device
Device listing number(s)		
Job reference number(s)		
E.g. Intended use	A comprehensive comparison of the next generation device with the registered device, including but not limited to the intended use/indications for use, design characteristics, mode of action/principles of operation, material/formulation, technical and performance specifications, packaging configuration, manufacturing process, sterilization method and process, compatible accessories/calibrators/controls/analyzers. This may be accompanied by pictures/diagrams with supporting text to highlight the differences.	
Indications		
Principles of operation		
Material		
Packaging		

NextGen MD Form

NextGen MD form

PART 2 JUSTIFICATION ON RELEVANCE OF PREVIOUSLY SUBMITTED DATA TO THE NEXT GENERATION DEVICE

Please note that only identical test reports (same report version) can be leveraged. Please include only relevant design verification and validation aspects that you wish to leverage in this section.

Design verification and validation	Filename of report(s)	Justification
E.g. Biocompatibility	List the exact filename of the report submitted in the application of the registered device(s). This same document with the same filename is to be submitted in the premarket application of the next generation device	A detailed critical analysis on why the next generation device may leverage on the data of the registered device(s). If multiple registered devices and/or device listings are to be leveraged on, please specify the device name and the associated device listing in the table to facilitate review.
Sterilization		
Shelf-life		
Analytical Sensitivity		
Analytical Specificity		

EXAMPLES THAT QUALIFY FOR THE NEXT GENERATION INITIATIVE

Example 1

	Next Generation Device	Registered device
Name	AAA	XXX
Device type	Coronary Stent	Coronary Stent
Intended use	Identical	
Material	Identical	
Design	Different strut design, and smaller in dimension	Different strut design, and bigger in dimension
Shelf life	Identical	
Sterile Packaging	Identical	
Sterilization method	Identical	
	Eligibility criteria	
Same product type	✓	
Identical biocompatibility validation	✓	
Identical sterilization validation	✓	
Identical shelf-life validation	✓	

- Identical packaging validation - YES
- Identical functional validation - NO

Example 2

	Next generation device	Registered device 1 (DE01234)	Registered device 2 (DE56789)
Name	AAA	BBB	CCC
Device type	Spinal cage	Spinal cage	Spinal cage
Intended use		Identical	
Material	Titanium + HA coating	Titanium	SS + HA coating
Design		Different shape	
Sterilization method		Identical	
Shelf life		Identical	
Sterile packaging		Identical	
		Eligibility criteria	
Same product type		✓	
Identical biocompatibility validation		✓ For titanium	✓ For HA coating
Identical sterilization validation		✓	
Identical shelf-life validation		✓ • Identical packaging validation - YES • Identical functional validation – NO	

Example 3

	Next generation device	Registered device
Name	AAA	BBB
Intended use	To quantify creatinine as an aid in diagnosis of renal disease and monitoring renal dialysis	To quantify creatinine as an aid in diagnosis of renal disease
Indications for use	Identical	
Formulation	Identical	
Labelled storage condition	Identical	
Indicated sample type	Serum + Plasma + Urine	Serum + Plasma
Analyzer	For use on XXX Analyzer	For use on YYY Analyzer
	Eligibility criteria	
Identical formulation AND labelled storage condition	✓	
Identical intended use and indications for use	✓ YES (To quantify creatinine as an aid in diagnosis of renal disease)	
Identical sample type	✓ YES (Serum + Plasma)	

No.	Questions	Answers
1	What is this initiative about?	This is not a new evaluation route. It is meant for new devices that do not qualify for change notification and have to be submitted via full evaluation route. In general, if there are changes to a medical device, applicants should first verify if change notification is applicable.
2	What is the submission route?	It must be submitted through full evaluation route. The relevant published turn-around-time (TAT) and fees will apply. Once approved, the NextGen MD will be listed separately on the Singapore Medical Device Register (SMDR).
3	Can we opt in this initiative for priority review applications?	Yes
4	If the NextGen MD has a different risk classification from the registered device, can I still opt-in for the NextGen MD initiative?	You can still qualify for the initiative, provided both NextGen MD and registered device meet the eligibility criteria.
5	What is the validity period of the documents that can be accepted? For example, packaging validation data for registered device was done 5 years ago. Is this still considered valid for use in the NextGen MD application?	The product owner is responsible to determine if the data is relevant and valid for the next generation device.
6	Do we need to resubmit the identical validation reports which have been previously submitted for registered devices? E.g. if the NextGen MD shares the same biocompatibility report as the registered device, do we still need to submit the biocompatibility report in the premarket application for NextGen MD?	The applicant is still required to submit the documents in the NextGen MD premarket application as per GN-15: Medical Device Product Registration, for the NextGen MD.

The End

Further questions:

Email: hsa_md_info@hsa.gov.sg

Subject: NextGen MD Initiative