2019-2020 RCC Work Plan: Medical Devices

Canadian Department: Health Canada, Therapeutic Products Directorate, Medical Devices Bureau
U.S. Department/Agency: FDA, Center for Devices and Radiological Health

Regulatory Cooperation Statement:
Health Canada and the U.S. Food and Drug Administration (FDA) will continue to work together on pre and post market regulatory convergence topics, including in particular, through the International Medical Devices Regulators Forum (IMDRF). The IMDRF aims to accelerate international medical device regulatory harmonization and convergence for regulators and stakeholders worldwide. Building upon existing regulatory harmonization initiatives, Health Canada and the FDA will work towards the development of the Medical Device Single Review Program (MDSRP) to improve patient access to medical devices, support innovation, and strengthen standards development. The MDSRP development process, pilot, and program launch will take place over two years from 2019 to 2021.

Work Plan:

Initiative	Desired outcome(s)	Activities	Reporting
The FDA and Health Canada will work bilaterally towards the development of MDSRP to harmonize pre-market technical review requirements for moderate risk medical devices. In parallel, FDA and Health Canada will continue to work through the IMDRF Good Regulatory Review Practices (GRRP) Working Group to develop harmonized premarket requirements which will serve as the foundation for future MDSRP work.	-Improve patient access to medical devices -Support innovation by decreasing barriers to entry by harmonizing regulatory requirements -Strengthen standards development by promoting the use and development of international consensus standards -Reduce pre-market review burden to focus resources on major public health issues -Share knowledge and resources across regulatory jurisdictions -Strengthen the confidence and consistency in the regulatory decision-making process	Definition of project scope (Spring 2019)	**Fall 2019:** Completed **Status update: The project scope was limited to moderate risk medical devices.**
		Selection of devices (Summer 2019)	**Fall 2019:** Underway – with challenges **Status update:** A preliminary scan indicates that eligible device candidates in radiology: x-ray, ultrasound, MRI. Additional devices for harmonization may also include cardiovascular device review panel and glucose monitors.

Initiative	Desired outcome(s)	Activities	Reporting
	-Strengthen commitment to Public Health Mission and ensure patients have access to safe and effective medical devices.	Pre-Pilot Proof of Concept (Summer 2019)	**Fall 2019:** Underway – on track **Status update:** FDA and Health Canada review teams are collaborating on the joint review of an oxygenator device which is FDA Class II and Health Canada Class III. FDA, Health Canada, and the medical device manufacturer have held multiple teleconferences and meetings to discuss pre-market technical requirements and similarities and differences in the regulatory jurisdictions. An analysis of this Pre-Pilot is expected by Winter 2020.
		Development of harmonized evaluation criteria (Winter 2020)	
		Development of harmonized labeling criteria, Spring 2020	
		Project Launch, Summer 2020	
		Project Completion, Spring 2021	

Initiative	Desired outcome(s)	Activities	Reporting
		Post Evaluation Completion, Summer 2021	