5 510(K) SUMMARY

5.1 510(k) Owner Information

Submittal Date:	04-JUNE-2018
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5.2 Device Information

Trade Name:	X-ray Imaging System for the McLaren Proton Therapy System
Common Name:	X-ray Imaging System, XIS
Classification Name:	Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code LHN)

5.3 Predicate Device

EhmetDx, LLC is claiming the X-ray Imaging System is substantially equivalent to the device listed in Table 5-1 Predicate Device. The predicate device was chosen based on the fact they have similar intended uses, principles of operation and are comparable in terms of identified performance and technological characteristics.

Device	510(k) Number	Indication for Use
IBA I_2C	K132847	I_2C is used with a charged particle or photon radiation therapy system for localization of the patient position with respect to the therapy equipment and to provide correction feedback to the radiation therapy system

Table 5-1 Predicate Device

5.4 Device Description

The X-ray Imaging System controls the x-ray generation, image processing and patient registration of the McLaren Proton Treatment System (K160063). The software product described by this document is considered a sub-system of the McLaren Proton Treatment System.

The software product integrates with the following components of the McLaren Proton Treatment System:

- X-ray generator & tube assembly

- Amorphous silicon flat-panel detector
- Electro-mechanical controls of the imaging c-ring to enable system positioning and rotation around the patient

The software will permit a radiation technician to set the desired energy levels and field of view. Once set the software can acquire orthogonal or CBCT x-ray images of the region of interest. When images are acquired the software will process them to create viewable images for patient location registration. The patient's position will be adjusted, if needed, based on a comparison of the current patient location, the defined treatment plan, and Digitally Reconstructed Radiographs or CTs.

5.5 Intended Use

The X-ray Imaging System is intended to be used as a patient setup and localization tool that is capable of processing orthogonal or CBCT images acquired at the start of the treatment. The images will be compared against Digitally Reconstructed Radiographs or CTs that were used to define the treatment plan. The comparison will generate position correction vectors if required and provide them to the McLaren Proton Treatment System for patient position corrections prior to treatment.

5.6 Technological Characteristics

There are several differences from the IBA I_2C and EhmetDx XIS devices. We do not foresee any of these differences materially impacting the safety or effectiveness of the X-ray Imaging System for the McLaren Proton Treatment System relative to patient setup and localization devices currently in commerce.

1. Similar to the predicate device, the XIS provides the following imaging and registration characteristics:
    a. Acquisition of 2D, 2D stereoscopic and 3D images
    b. 3D images generation by acquiring images while imaging hardware is rotated around the desired volume. The acquired images are then reconstructed using broadly used algorithms to create a 3D volume.
    c. Registration capabilities for 2D2D, 2D3D, and 3D3D for position localization and correction vector generation
    d. Data coordination with external 3rd party systems for data pushes and pulls in conformance with DICOM standards.

2. While the IBA I2C is a fully integrated hardware and software platforms, the EhmetDx XIS is a software platform. As a software platform the XIS is designed for exclusive integration with the McLaren Proton Treatment System. A major design feature of the McLaren Proton Treatment System is its modular approach to subsystem integration. This modular design allows the McLaren Proton Treatment System to update aspects as technology and products improve over time. The XIS will introduce CBCT localization capabilities to the already approved orthogonal capabilities.

3. The X-ray Imaging System for the McLaren Proton Treatment System interfaces with a Varian 4030CB 40cm × 30cm image receptor whereas the IBA I_2C uses the Thales Pixium 43cm × 43cm imaging detector. Both detectors have been used for radiography and CBCT. The major difference is the larger size of the Thales detector can provide a larger axial field-of-view (FOV). However, the site of treatment is well known in advance and the irradiated field-of-view from the imager should be minimized as much as practical to reduce radiation dose. In addition, the larger cone angles associated with the increased axial FOV will result in more severe incomplete data artifacts for these circular orbit systems. The larger image receptor, while a nice feature, does not offer much practical advantage over the use of the Varian 4030CB.

4. While IBA system offer integrated registration software, the X-ray Imaging System for the McLaren Proton Treatment System generates DICOM output files that are then used by the 3rd party 510(k) approved MIM registration software to determine the appropriate correction vector for patient setup. MIM Software, Inc. is primarily a medical software company and has the advantage that it can devote (and has devoted) significant effort to ensuring that the registration interface works seamlessly and accurately. Presently the MIM 4.1 registration software is listed under 510(k) K001276 and K071964.

5.6.1 Features and Characteristics

Features and Characteristics	EhmetDx XIS	IBA I_2C (K132847)
Indications for Use		
Verification of patient setup and positioning	✓	✓
Used with charged-particle radiation therapy system	✓	✓
Used with photon radiation therapy system	✓	✓
Image Acquisition		
kV imaging with large-area flat-panel	✓	✓
Stereoscopic radiographs	✓	✓
Conebeam CT	✓	✓
Flexible use of different x-ray tubes and imaging panels	✓	✓
Image matching (with 3rd party MIM software – 510(k) K001276, K071964)		
Registration using anatomical landmarks	✓	✓
Registration using fiducial landmarks	✓	✓
Registration using CBCT with planning CT	✓	✓

Features and Characteristics	EhmetDx XIS	IBA I_2C (K132847)
Registration using radiographs with DRRs created from planning CT	✓	✓
2D2D (5 DOF registration)	✓	✓
2D3D (6 DOF registration)	✓	✓
Interface with 3rd party applications		
DICOM exchange of clinical and imaging data	✓	✓
Transfer of patient position correction vector	✓	✓

5.6.2 Technical and Performance Specifications Comparison

Technical and Performance Specifications	EhmetDx XIS	IBA I_2C (K132847)
Specifications defined through integration with the McLaren Proton Treatment System		
X-ray generator operating range (radiographic)	40–150 kVp	40–150 kVp
Flat panel imaging receptor manufacturer	40–150 kVp	60–125 kVp
Used with photon radiation therapy system	Varian	Thales
Flat panel pixel size	194 µm	148 µm
Flat panel pixel detector dimensions	40×30 cm	43×43 cm
Active imaging area	39.7×29.8 cm	42.0×42.5 cm
Flat panel pixel array size	2048×1536	2874×2840
X-ray Imaging System Specifications		
CBCT distance accuracy	≤1%	1%
CBCT spatial resolution	≥5 lp/cm	≥5 lp/cm
CBCT low-contrast resolution	15mm@1%	15mm@1%
CBCT CT number accuracy	±40 HU	±40 HU
CBCT CT number uniformity	±40 HU	±40 HU

5.7 Non-clinical Testing

The device underwent full design testing that included unit integration, verification, and validation testing to ensure all design requirements and risk measures were properly implemented and effective. Imaging performance and radiography and cone beam CT was assessed using standard measurement tools and phantoms and passed all tests. Additional testing was conducted to establish data for predicate comparison.

5.8 Clinical Testing

EhmetDx did not perform clinical testing for the X-ray Imaging System and no clinical data was collected during device validation activity and substantial equivalence testing.

5.9 Testing Conclusion

The testing performed and their results confirmed the system performed as designed, has similar performance characteristics as the predicate device, and is safe and effective for patient use.