



**NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

October 30, 2018

Eddie Beard
810 Fairgrove Church Road SE
Hickory, NC 28602

Exempt from Review – Replacement Equipment

Record #: 2742
Facility Name: Catawba Valley Medical Center
FID #: 933080
Business Name: County of Catawba
Business #: 2949
Project Description: Replace Interventional Radiology Equipment
County: Catawba

Dear Mr. Beard:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 5, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7), therefore, you may proceed to acquire without a certificate of need the Siemens Artis Zee interventional radiology system to replace the Siemens Artis Axiom interventional radiology system. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency’s Construction, Radiation Protection and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Ena Lightbourne
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 2701 Mail Service Center, Raleigh, NC 27699-2701
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3750 • FAX: 919-733-2757



CATAWBA VALLEY MEDICAL CENTER



October 5, 2018

Ms. Martha Frisone
Chief, Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Interventional Radiology Equipment Replacement at Catawba Valley Medical Center/Catawba County

Dear Ms. Frisone:

Catawba Valley Medical Center (CVMC) intends to replace its existing Siemens Artis Axiom interventional radiology (IR) system located in our hospital in Hickory. Pursuant to NCAC 14C .0303(a), CVMC requests confirmation that this IR equipment replacement lies within the definition of NCGS 131E-176(22a) and the regulations set out in NCGS 131E-184(a)(7) and NCAC 14C .0303, as exempt from review.

CVMC began using the Siemens Artis Axiom IR system in 2006, and intends to replace it with a new Siemens Artis Zee multi-purpose IR system. The Artis Axiom has been operating daily, used for ED patients as well as inpatients and other outpatients. The current system is 12 years old and has reached the limit for upgradability in software configuration, and has had multiple out-of-service incidents during the past year.

Via this letter, CVMC affirms that it will trade-in the Artis Axiom system to Siemens, for removal from operation at CVMC. Siemens intends to either scrap the IR equipment or refurbish and sell the equipment to another end user. If Siemens sells the system to another user in North Carolina, it understands that any applicable CON requirement must be met.

Pursuant to NCGS 131E-184(a)(7) *"The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."*

NCGS 131E-176(22a) defines "replacement equipment" as "equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced".

Applicable Regulations

NCAC 14C .0303 defines "comparable medical equipment" as equipment that is functionally similar and which is used for the same diagnostic or treatment purposes. Replacement equipment is comparable if:

- (1) it has the same basic technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first 12 months after replacement equipment is acquired.

Compliance

CVMC hereby certifies that:

1. The total project cost for the interventional radiology system replacement, including the equipment, space renovation, furniture, rigging and installation, and all other costs, is \$1,100,000, as shown in Attachment A. Please refer to Attachment B for the Siemens equipment quote. CVMC will locate the replacement IR system in the existing IR equipment room in the hospital. CVMC's General Contractor confirms that relatively modest renovation is required to accommodate the replacement IR system. The cost to remove the existing Artis Axiom system from CVMC will be borne by Siemens, and Siemens is including delivery, rigging, and installation costs in the sale price of the new Artis Zee system.
2. The replacement interventional radiology system will be installed at CVMC for the sole purpose of replacing comparable IR equipment currently in use, which will be relocated out of CVMC. A comparison of the existing and replacement equipment is provided in Attachment C.
3. The replacement IR system is functionally similar to the existing IR equipment and will be used for the same therapeutic procedures as the IR equipment currently in use. The replacement equipment is a full-featured interventional radiology system, with features that do not change the basic technology or result in the provision of a new health service or type of procedure.

4. No increase in charges will occur within the first twelve months after the replacement interventional system is acquired.
5. The average cost per procedure will not increase by more than 10% during the initial 12 months of service as a result of the IR equipment replacement.

CVMC requests that the Division of Health Service Regulation confirm that replacement of the interventional radiology system as proposed herein does not constitute a new institutional health service and is exempt from certificate of need review.

Please contact Aarti Sura, Vice President, at 828.732.7162 regarding any questions concerning this request.

Sincerely,



Eddie Beard
President & CEO

Attachments: A - Proposed Capital Cost
B - Vendor Equipment Quote
C - Equipment Comparison

Attachment A: Proposed Capital Cost

Attachment A

PROPOSED CAPITAL COST

Project name: Interventional Radiology System Replacement
 Proponent: Catawba Valley Medical Center

A. Site Costs	
(1) Full purchase price of land # Acres ___ Price per acre _____	
(2) Closing costs and legal fees	
(3) Site inspection and survey	
(4) Site preparation costs	
(5) Other	
(6) Subtotal Site Costs	\$0
B. Construction Contract(s)	
(7) Cost of construction contract(s)	\$200,000
(8) Other	\$0
(9) Subtotal construction contract(s)	\$200,000
C. Miscellaneous Project Costs	
(10) Building purchase	
(11) Equipment & furniture not included above	\$866,000
(12) Consultant fees	
Architect & engineering fees	\$10,000
Certificate of need preparation	
Legal fees	
Market analysis	
Other	
Subtotal consultant fees	\$10,000
(13) Financing costs	
Bond	
HUD	
Commercial loan	
Other (specify)	
Subtotal financing costs	\$0
(14) Interest during construction	\$0
(15) Other (contingency)	\$24,000
(16) Subtotal miscellaneous project costs	\$900,000
Total Capital Cost of Project	\$1,100,000

Attachment B: Vendor Equipment Quote

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355
Fax: (866) 309-6967



SIEMENS REPRESENTATIVE
Mathew Hayes - (336) 263-4273

PRELIMINARY PROPOSAL

Customer Number: 0000005129

Date: 12/6/2016

CATAWBA VALLEY MEDICAL CTR
810 FAIRGROVE CHURCH RD
HICKORY, NC 28602-9617

Artis zee ceiling system with PURE

Cath/EP system

Quote Nr: 1-H16U4Q Rev. 0

Artis zee ceiling

All items listed below are included for this system: (See Detailed Technical Specifications at end of Proposal.)

Qty	Part No.	Item Description
1	14445998	Artis zee ceiling Interv. Card. Artis zee ceiling for interventional cardiology now features PURE(r). PURE adds smooth interaction to Siemens' smart technologies. It is designed to boost productivity and enhance outcomes for certain clinical applications while increasing image quality and reducing dose. The ceiling-mounted C-arm offers highly flexible positioning. The motorized rotation of the C-arm from a head-end position to a lateral position allows for free head access and full patient coverage without rotating the table. The patient table is fitted with a freely movable patient positioning tabletop. The Megalix Cal Plus X-ray tube with flat emitter technology enables small focus sizes and strong, short X-ray pulses. The as20 flat detector is optimized for cardiology end allows for steep angulations. Frame rates up to 30 f/s and functions for displaying and storing ECG curves are included. The complete CARE+CLEAR package offers optimal image quality at the lowest reasonable dose. Live and reference images are displayed on two 19" flat screens in the exam room. In the control room live images are displayed on a third screen.
1	14432820	DR acquisition mode Digital acquisition technology with frame rates of 0.5 to 7.5 f/s in 1k/12 bit matrix and digital real-time filtration. Single image and serial acquisitions with time-controlled and manually variable frame rate.
1	14432947	Fluoro Loop Storage and review of dynamic fluoroscopic sequences (Fluoro Loop). This saves an additional acquisition and reduces dose. The maximum storable fluoroscopic time depends on the selected pulse rate, e.g. 34 s at 30 p/s, 68 s at 15 p/s.
1	14432942	LV Analysis Analysis of the left ventricular function of the heart.
2	14432953	Lower body radiation protection This radiation shield protects the user from scattered radiation when standing at the table side. It can be attached to the accessory rails either on the right or on the left side of the patient positioning table. It provides the user an additional accessory rail.

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
		<p>It includes a basic unit (71.5 cm x 75 cm/ 28.2" x 29.5" (l x w), 7.7 kg/ 16.98 lb), one lower body radiation protection pivot swivel element (77 cm x 48 cm/ 30.3" x 18.9" (l x w), 3.8 kg/ 8.4 lb) and three clip-on units (57 cm/ 22.4" x 33 cm/ 12.99" (l x h), 2.2 kg/ 4.85 lb; 27 cm/ 10.6" x 33cm/12.99", 0.9 kg/ 1.98 lb and 27 cm/ 10.6" x 25cm/9.8", 1 kg/ 2.2 lb) with a lead of 0.5 mm/ 0.02" Pb. The maximum weight of the accessory rails is 40 kg (88.2 lb).</p> <p>Product may not be used in conjunction with a TRUMPF or MAQUET surgery table.</p>
1	14434157	<p>Moveable upper body rad. protection This radiation shield protects the user from scattered radiation. For room heights up to 290 cm/ 114.2". It includes a ceiling rail (4m/ 157.5"), a ceiling mounted and movable stand (80 cm/ 31.5"), a support arm (75 cm x 90 cm/ 29.5" x 35.4") and an acrylic glass. The shield is made of acrylic glass with lead equivalent of 0.5 mm (w x h: 61 cm x 76 cm/ 24" x 29.9"), which can pivot and rotate around a fixed point with a range of 360 degrees. Weight acrylic glass: 9 kg/ 19.8 lb. Weight support arm: 10 kg/ 22 lb. The operation range is limited when used with Artis floor/biplane MN.</p>
1	14440512	<p>LED Exam Light Ceiling-mounted, flexible positionable examination light with focusable light system. It is fully integrated into the ceiling-installed radiation protection mounting unit. - Luminance: 60.000 Lux for 100 cm/ 39.4" distance - Working distance: 70 to 140 cm/ 27.6" to 55.1" - Color rendering index Ra at 4500 Kelvin: 95 - Color temperature: 4,300 Kelvin - Focusable light field: 14 to 25 cm/ 5.5" to 9.8" - Diameter of light head: 33 cm/ 13" - Number of LEDs: 19 - Total input power: 20 VA</p>
1	14443011	<p>Large Display diagn. Protection The high quality laminated glass protective screen protects the panel of the monitor against mechanical damage and fluid ingress on the front. It is suited for clinical image evaluation. Features: The laminated glass enforces high mechanical strength and resistivity against mechanical impact, the special coating reduces reflections for a continuous image quality, excellent spectral transmission of at least 98%, can be added to existing Artis Large Display installations. Weight: approx. 12kg (55") up to 16kg (60")</p> <p>Note: Observe the maximum permissible load of the display suspension, a combination with other options mounted to the display suspension might be restricted.</p>
1	14432950	<p>DICOM RIS-Modality Worklist Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).</p>

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40 Liberty Boulevard, Malvern, PA 19355
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Mathew Hayes - (336) 263-4273

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14434200	<p>Interface for existing Sensis Bi-directional communication interface (incl. set of cables) between Artis zee/Artis Q/Artis Q.zen and the Sensis hemodynamic and/or electrophysiology recording system.</p> <p>Contains an adapter cable for SVGA on 5x BNC.</p> <p>Recording, storage, and display of an ECG lead. Displayed together with the image information on a single monitor.</p>
1	14434172	<p>Large Display Preparation for the large color flat screen display on a ceiling-mounted, longitudinally mobile, swiveling, rotating, and height-adjustable display holder in the examination room.</p> <p>Note: If a Large Display is selected, the Artis basic configuration includes a connection kit for the Large Display instead of the displays for the examination room. The type of large display can be chosen with a separate position.</p>
1	14434176	<p>Large Display video controller 18 Large Display Video Controller 18 is the middle of three different video controller sizes. A maximum of 18 video signals can be connected and displayed simultaneously on the Large Display. The Large Display video controller 18 receives various internal and external video signals for presentation to scale on the Large Display. Up to 18 external and internal video sources can be connected (max. 14 DVI-D and 4 analog (VGA) channels).</p>
1	14443012	<p>LD High Contrast panel size 55" Large color flat screen display (including cables) for the examination room, with a panel diagonal of 55". This large display version provides an excellent clinical image quality due to its new IPS panel technology.</p>
1	AXA_INITIAL_3 2	<p>Initial onsite training 32 hrs Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.</p>
1	AXA_FOLLOW UP_24	<p>Follow-up training 24 hrs Up to (24) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.</p>
1	AXA_FOLLOW UP_12	<p>Follow-up training 12 hrs Up to (12) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.</p>
1	AXA_PURE_E SSCL	<p>AX Artis PURE Essential Class Tuition for (1) imaging professional to attend Siemens class at Siemens Training Center. The Artis PURE Essentials Course is a 3.5-day classroom course beginning on Tuesday at 8:30 a.m. and ending on Friday at 12:00 p.m. It is designed to provide the participant with an in-depth knowledge of the essential functions of the Artis system as well as the skills needed to perform these functions. Through the use of demonstrations, lectures, and hands-on lab experience using an Artis system, participants will learn Artis system principles and workflows of patient examinations. Additionally, participants have the opportunity to meet other users and share their experiences and solutions to various challenges of the IR, cath lab, and the Hybrid OR environment. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed by the later of (12) months from purchase or</p>

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PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
		Install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	AXA_ECLASS	e.class-Virtual Instructor Led Training AXA_ECLASS Tuition for up to (4) imaging professionals to participate in a Siemens instructor led virtual class. The virtual setting allows the participant to benefit from classroom training without the need to travel to a Siemens training center. This educational offering must be completed (12) months from Install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
2	NT60010635	Blue anti-fatigue floor mat for hospital
1	AXA_RIG_ZEE SP_STD	Standard Rigging zee SP
1	AXA_BUDG_A DDL_RIG	Budgetary Add'l/Out of Scope Rigging \$15,000
		System Total: \$866,000

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PRELIMINARY PROPOSAL

OPTIONS on Quote Nr: 1-H16U4Q Rev. 0

OPTIONS for Artis zee ceiling

All items listed below are OPTIONS:

Qty	Part No.	Item Description	Extended Price
1	14432905	4P wireless footswitch inst. of cbl Wireless footswitch connection Note: Wireless replaces the wired connection.	+ \$2,949
1	14434237	Shielding kit, as20 Kit for shielding of electromagnetic fields (180 Hz) of the X-ray tube to avoid interference with the EP Measuring system, as well as for shielding the flat detector.	+ \$1,087
1	14434169	CLEARstent Live CLEARstent Live is a real-time stent enhancement tool and provides a stabilized view of the moving stent which is displayed on the Assist/Reference Monitor. CLEARstent Live allows real-time verification of stent positioning while moving the device. This enables the physician to precisely position the stent in relation to the anatomy of the heart and stents that already have been implanted. Contains both CLEARstent Live license and CLEARstent license. The CLEARstent imaging function allows an improved display of fine stent structures, i.e. the grid of inflated stents. CLEARstent is a post-processed stent enhancement and may be used also on previously acquired images. Using the CLEARstent function special reference images from any scene or fluoroscopy scene acquired natively will be generated. Composite images are created by averaging several frames of a scene and by considering the alignment of balloon markers. If an ECG signal is available, the heart phase will also be taken into account.	+ \$11,899
1	14432957	ECG-triggered FL R-wave-triggered fluoroscopic pulse release for motion reduction also for low pulse rates.	+ \$10,293
1	14440411	Intercom - Comfort Intercom system for communication between examination room and control room. It includes - a microphone with a control box for the control room - a microphone with an adaptive acoustic filter for background noise suppression for the examination room - a footswitch for conversation selection for the examination room The microphone of the examination room is installed on the ceiling.	+ \$1,188
1	14434168	IVUSmap With IVUSmap, it is possible to coregister intravascular ultrasound images and X-ray images on the Artis system. ECG-triggered Fluoro license is included. With this item, a display is delivered additionally for the examination room if an Artis Large Display was not ordered. If an Artis Large Display is ordered, the configuration includes a connection kit for the Artis Large Display instead of the 19" display.	+ \$13,073

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Qty	Part No.	Item Description	Extended Price
1	BART700PEDL	<p>Mark 7 Arterion, Pedestal System</p> <p>The Arterion Mark 7 Pedestal contrast medium injector can be positioned anywhere at the patient positioning table on a mobile unit, for direct operation of all functions in the examination room.</p> <p>The injector system includes: A mobile pedestal stand with electronics unit, a contrast medium heater and a connection cable to the manual release. A support arm with injector head and a control lever for moving the injector head. A user control console with large touch screen and corresponding additional monitoring display on the injector head.</p> <p>Functions Pressure limitation. for 150 ml syringes 689 to 8273 kPa, corresponds to 100 to 1200 psi. .</p> <p>Flow rates for 150 ml syringes. 0.1 to 45 ml/s in increments of 0.1 ml/s 0.1 to 59.9 ml/min in increments of 0.1 ml/min rise/fall: 0 to 9.9 s in increments of 0.1 seconds</p> <p>Release delay for injection or radiation: 0 to 99.9 s in increments of 0.1 s.</p> <p>Adjustable volume for 150 ml syringes: 1 ml to the max. syringe capacity in increments of 1 ml.</p> <p>Fill rate: Variable syringe filling speed 1-20ml/s.</p> <p>Injection protocols: Up to 40 injection protocols possible.</p> <p>Parameters currently displayed on the touch screen display and on the head display: Injection speed Injection volume Remaining volume Injection duration Applied pressure</p> <p>Contrast medium heating: Nominal 35°C (95°F)±.5°C (9°F)</p> <p>Injection data memory Up to 50 injection data items stored</p> <p>Included in the scope of delivery Injector standard configuration 150 ml SIEMENS interface cable Operator Manual</p>	+ \$27,067

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PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
		Service manual (English)	
		Power supply 200 V to 250 V, 50/60 Hz.	
1	BINSART700P EPW935515UP	Arterion Pedestal Install	+ \$1,545
1	S	Eaton Powerware 9355 15 kVA UPS	+ \$20,801

Includes UPS, battery, maintenance bypass panel, and one year on-site parts and labor coverage (24x7) by Eaton Powerware. This UPS is recommended when protection and uninterruptible power is required for the Artis' C-arm and table. Emergency fluoroscopy is not available with this UPS. If emergency fluoroscopy is required, the 9390 - 160 kVA UPS is recommended for the full system. One UPS per lab.

Additional seismic brackets are required to make this system OSHPD approved.

FINANCING: The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

Siemens Healthcare

Mathew Hayes
(336) 263-4273
mathew.hayes@siemens.com

Attachment C: Equipment Comparison

Attachment C

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Interventional Radiology	Interventional Radiology
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating of MRIs	NA	NA
Model Number	Artis Axiom	Artis Zee
Serial Number		Unknown
Provider's Method of Identifying Equipment	NA	NA
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN#	NA	NA
Mobile Trailer Serial Number/VIN#	NA	NA
Date of Acquisition of Each Component	04/28/2006	Target October 2018
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New when acquired	New
Total Capital Cost of Project (Including Construction, etc.)	NA	\$1,100,000
Total Cost of Equipment	\$1,265,653	\$866,000
Fair Market Value of Equipment	\$0	NA
Net Purchase Price of Equipment	\$1,265,653	\$866,000
Locations Where Operated	810 Fairgrove Church Road, SE, Hickory, NC	same
Number Day in Use/To be Used in NC per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	No increase
% Change in per Procedure Operating Expenses (by Procedure)	NA	No increase
Type of Procedures Currently Performed on Existing Equipment	Interventional Radiology	NA
Type of Procedures New Equipment is Capable of Performing	NA	Interventional Radiology