STERLING
Diagnostic Imaging, Inc.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information
is being submitted in accordance with the requirements of
SMDA 1990 and 21 CFR 807.92.

SUBMITTED BY:

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DEVICE NAME:

LINX™ Networking System

PREDICATE DEVICE:

LINX™ Networking System with LINX™ Laser Imager (K900935)

DEVICE DESCRIPTION AND INTENDED USE:

This Premarket Notification 510(k) is being filed to cover
additions to the LINX™ Networking System with LINX™ Laser
Imager (K900935) to include all capabilities that we are
adding to meet market demands. The basic product concept
remains - to connect various image input devices to one or
more output devices. That basic concept has been expanded to
meet market demands:

>   new image source interfaces
>   new control interfaces
>   new network interfaces
>   more output devices supported
>   new data types managed
>   image transfer mechanisms
>   (some output devices may require handling
>   in the transmission path to the output
>   device to compensate for differences in
>   devices)

DEVICE COMPARISON TO PREDICATE DEVICE:

The LINX™ Networking System is substantially equivalent to
the LINX™ Networking System with LINX™ Laser Imager
(K900935) as summarized below:

Characteristic	LINX Networking System	LINX Networking System (Expanded)
Image Sources		
video	X (up to 45Mhz pixel clock speed)	X (up to 160Mhz pixel clock speed)
digital interface	X	X
digitizer interface		X
computed radiography int		X
removable media		X
network interfaces		X
DICOM Devices		X
Network connections		
token - ring	X	X
ethernet		X
ATM		X
FDDI		X
protocols		
QNX	X	X
TCP/IP		X
Interface methods		
point - point	X	X
network	X	X
LAN	X	X
WAN		X
Operator Interfaces		
hardware keypad	X	X
Windows		X
remote host		X
Data Types		
image	X	X
text	X	X
patient info		X
Output devices		
LINX Laser Imager	X	X
3M 952	X	X
3M 831	X	X
3M 969	X	X
LP400	X	X
home telerad systems		X
DICOM Devices		X
File systems		X

Characteristic	LINX Networking System	LINX Networking System - (Expanded)
Accessory Device Interfaces		X
Densitometer		X
Bar Code Entry		X
Statistics Reporting	X	X
Usage data		X
transmission	X	X
Image transfer mechanisms		
straight thru	X	X
crop		X
LUT	X	X
sharpness filter		X
interpolate		X
decimate		X
compress (lossless)		X